

“SOMETIMES THERE ARE DIFFERENCES OF OPINION AS TO WHAT THE
DATA MEAN”: BUREAUCRACY AND FACTICITY IN THE FACE OF
INCONCLUSIVE SCIENCE

by

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ABSTRACT

Bureaucratic rhetorics have been largely overlooked in rhetorical scholarship, in part because of an assumed synonymy between bureaucratic approaches, purposes, and language uses and political ones. This dissertation applies rhetorical analysis to a case study of bureaucratic rhetoric—the 2011 U.S. Food and Drug Administration (FDA) hearing on the breast cancer indication for the drug Avastin—to identify characteristic rhetorical strategies of bureaucracy and how these differ from the strategies of political rhetoric. In particular, I investigate the rhetorics that bureaucracies use to make sense of science in the context of regulatory decision making. Given that science is often used to support bureaucratic decisions, and that bureaucracy is involved in most aspects of scientific and medical research, the interactions between the two are of particular importance. Specifically, this project addresses three questions: (1) what are the characteristic rhetorical strategies of bureaucratic institutions; (2) who or what is the audience of bureaucratic rhetoric; and (3) what are the implications of these findings for bureaucratic institutions themselves, the public, science and medicine, and rhetorical theory?

In the first part of the analysis, I investigate questions about how bureaucracy legitimizes its decisions. In the second part, I argue that one of the reasons for the disconnect between the public and the FDA is that bureaucracies, including the FDA, do not in fact address the public. Unlike political rhetorics, which address the public (and

“representatives” of the public, such as lobbyists), bureaucratic rhetorics address an internal audience of the bureaucracy itself. They do so through the medium of “the record.” In addressing “the record,” a bureaucracy will (and the FDA does in this hearing) attempt to achieve “facticity” (the appearance or status of being taken for granted as fact) for its own desired, and often predetermined, outcomes. Thus, the primary finding of this study is that as a science-based regulatory bureaucracy, the FDA cannot allow “differences of opinion as to what the data mean.”

This work is dedicated to John Carl Badila,
with unbounded gratitude and in very partial recompense
for his unflagging support.

“In spite of the great successes explaining the very large and very small, fundamental physics, and more generally, scientific reductionism, have been notably mute in explaining the complex phenomena closest to our human-scale concerns.”

—Melanie Mitchell, *Complexity: A Guided Tour*

“To make the right decisions, we thought, all we had to do was rely on indisputable knowledge. Now we must take decisions—no one can avoid doing so—just when we are plunged into the greatest uncertainty.”

—Callon, Lascoumes, and Barthe, *Acting in an Uncertain World: An Essay on Technical Democracy*

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CHAPTER 1

INTRODUCTION

Avastin (the trade name for Genentech's pharmaceutical bevacizumab) is one of a new category of cancer drugs. Unlike traditional chemotherapy agents, which work by killing cells directly (and often kill healthy cells as well as cancerous ones), these new drugs, called angiogenesis inhibitors, cut off the blood supply to tumors, inhibiting their growth and slowing or stopping metastasis. Avastin was in fact the first angiogenesis inhibitor approved by the FDA when it was approved in 2004 for the treatment of metastatic colorectal cancers. In 2006, Avastin was approved for the treatment of metastatic Non-Small-Cell Lung Cancer. Currently, Avastin is also approved for glioblastoma and metastatic renal cell carcinoma. While some scientific debate occurred, as is typical, during the approval processes for these "indications" (the FDA does not approve pharmaceuticals, per se; it approves the use of certain pharmaceutical agents for certain "indications," such as a particular type of cancer), the drama that ultimately placed Avastin at the heart of a controversy began in 2008, with its accelerated approval for metastatic breast cancer.

Although the accelerated approval process itself has been the subject of debate since its inception, that process was not the subject of the debate about Avastin, nor was it the cause of the controversy. The cause of the controversy—and the element of the Avastin debate that makes it not only indicative of a set of fast-advancing problems for

the FDA, but also typical of the kinds of debates occurring between American citizens and the bureaucracies meant to serve them—is scientific ambiguity. When the FDA began in the late 1930s, its decisions were, scientifically speaking, rather straightforward. For example, the case that led to initial public support for the agency involved widespread poisonings due to diethylene glycol, essentially antifreeze, in an over-the-counter antibiotic “elixir” (United States Department of Agriculture [USDA], 1938). To call for safety measures such as scientific and clinical testing of medicines in the face of such overt disregard for patients’ safety was both an obvious and a well-received move. In other words, the *bureaucratization* of the pharmaceutical-approval function of public health was timely and widely lauded.

To say that the creation of the FDA through the United States Federal Food, Drug, and Cosmetic Act of 1938 was a bureaucratization of a certain public health function is to say that a decision previously left to individuals (including doctors and pharmacists but also “patent drug” salesman and individual purchasers of medicines) was handed to a government institution that would employ a very particular decision-making process in a very particular way. Max Weber, perhaps the earliest and certainly the most thorough and best-known sociologist of bureaucracy, defines bureaucracy as an institution with five characteristics: rule-based action, organization around roles in which individuals are interchangeable, reliance on “the record,” reliance on expert opinion, and an homogenization of individuals. In other words, bureaucracy works by applying pre-determined, calculable, and universal rules to a set of homogenized individuals (on the assumption that a large group, or population, of individuals can be treated as if undifferentiated). These rules are applied by agents of the organization who are defined

by their roles in it (and who can, at any time, be replaced by others with similar credentials who will play the same roles) and whose procedures in making decisions are based on the institution's "record" of its previous decisions and procedures. Bureaucratic decisions are also based on the opinions of experts (who are in turn defined *as* experts by their role in the institution) who, by virtue of their credentials and roles, are accorded legitimacy in making decisions for the population at large. If certain elements of this definition appear circular or self-supporting, that is no accident; as we will see, two of bureaucracy's most prominent characteristics are its self-supporting nature and its tendency to speak almost exclusively to and for itself.

In 1938, the bureaucratization of a key function of public health was typical of a move toward bureaucratization generally, and also made considerable sense in light of the patent medicine movement and the totally unregulated nature of medical sales. Although the deaths of nearly 100 people by poisoning in the sulfanilamide elixir case was a prominent example of the danger of the unregulated medicines market, it was by no means the only example, and some response by government agencies toward increased safety was not only necessary but eagerly sought by citizens' groups. The creation of an entity that could test drugs in broad studies, certify certain agents as safe, and also keep unsafe agents off the shelf made perfect sense—just as the procedures put in place by the agency during the years following its inception made sense as a response to the previous unregulated period and to the clear-cut nature of such dangers as diethylene glycol.

However, in the 75 years since the sulfanilamide elixir poisoning, pharmaceuticals regulation has changed in unanticipated ways. First, in the 1960s, the FDA's purview changed radically, with the introduction of a new rule that the agency had

to test not only the safety of new agents, but their efficacy. The work, the calculations, and the roles of the agency became far more complicated almost overnight—so much so that the FDA had to create a committee system whereby outside experts advised the decision-making bodies within the agency itself. Efficacy is a more complex, more ambiguous, and harder to prove concept than safety, and the randomized clinical trials used to demonstrate efficacy can take several years and still lead to results that can be interpreted in multiple ways.

The second change since the 1930s is that pharmaceutical makers have begun creating new chemical compounds in a way that was never possible before, compounds not based on plants or other natural bases but wholly constructed in laboratories. Many of these compounds—Avastin among them—are so specifically targeted, so focused on particular biological processes, that it is hard to find sufficient patients for clinical trials. In addition, many of them—again, Avastin among them—are targeted to diseases that are rare or have very poor prognoses, meaning that the standard for efficacy is both lower and less clear. In the specific kind of metastatic breast cancer for which Avastin received accelerated approval, for example, the prognosis is almost certain death, often within a few months. In such a situation, the bar for approval is lowered, although not necessarily in clearly defined or officially documented ways. Many of these diseases, moreover, are hard to cure specifically because they manifest very differently in different individuals, meaning that, potentially, a drug that works for some patients with a particular condition may not work for other patients with the same condition. Finally, some drugs are now being presented to the FDA that are literally personal: they are created from the patient's

own tumors. By definition, such drugs cannot undergo large-scale safety tests or randomized clinical trials.

What this new pharmaceutical complexity means is that the bureaucratic decision-making processes devised in the 1930s, and the rhetorics by which they are supported, justified, and documented, are no longer perfectly relevant to many of the new compounds or to the individualized responses of highly complex diseases to those compounds. However, bureaucratic agencies like the FDA continue to apply those decision-making processes as if no change in the science of disease or pharmacology had occurred and as if their decisions were no more complicated than those made in the 1930s. This leads to situations in which a bureaucratic agency like the FDA applies its calculable-rule-based population-level procedures to uncertain, complex, individualized pharmaceuticals decisions through a rhetoric of facticity.

Facticity (also called Fact-Like Status) was characterized by Bruno Latour and Stephen Woolgar (1979). They argued that facts do not exist separately from statements made about them, but that instead “facticity,” or the status of being taken for granted *as* fact, is achieved through series of statements in which modalities—references to the circumstances in which the fact was produced, and to the fact that it *was* produced—are erased, leaving “the fact” standing alone, as if simply existing in the world. As Latour and Woolgar put it, “There is [...] an essential congruence between a ‘fact’ and the successful operation of various processes of literary inscriptions” (p. 76). A statement achieves its “Fact-Like Status,” or facticity, through those processes of inscription. To say that bureaucracies employ a rhetoric of facticity is, in short, to argue that facticity itself is considered ultimately (and perhaps solely) persuasive in that rhetoric, and also to

say that the rhetorical processes and strategies by which a bureaucracy achieves its ends are processes of achieving facticity—of achieving Fact-Like Status for certain claims through series of statements that eliminate modality.

Facticity and its operations in rhetorical terms are discussed in much greater detail in Chapter 4. For now, it is enough to say that the FDA's rhetoric of facticity both *assumes* and *claims* that not only should decisions be made on a scientific basis (which even those who disagree with the FDA's decisions do agree with), but that there *is a scientific basis* for *every decision* made by the agency—that scientific facticity is always achievable. This requires that the bureaucracy not only assume but also “prove,” at least to its own satisfaction, that factual evidence has been found and that it clearly supports the decision made. The FDA approaches its decision making with this assumption even in cases, such as the Avastin case, in which there literally is no such thing as “the science” on the issue. Regulatory agencies around the world, studying the same evidence, have come to different decisions about Avastin. Doctors who spoke at the Avastin hearing that is the subject of this study disagreed about the evidence and its meaning. Even given the tens of thousands of pages of evidence produced over the many years in which Avastin has been studied, questions still exist even about the indications for which it *is* approved—and agreement on the facts themselves, much less what they mean, certainly does not exist in relation to Avastin and breast cancer. At the same time, however, the bureaucracy's rhetoric assumes that there is a clear basis of scientific finding for their decision and that it is the only scientific finding of value (the only “legitimate” scientific finding), an approach that works to support and reify the

bureaucratic approach to public health, *not* to achieve any meaningfully scientific foundation for the decision.

All of which returns us to the Avastin controversy. In 2012, the accelerated approval for Avastin's breast cancer indication was revoked. An outcry from patients erupted in response, and after fighting against it for months, the FDA finally scheduled a hearing about the withdrawal. After more fighting, the agency allowed public speakers to present their opinions at that hearing—the transcript of which is the primary object of study in this project. My analysis will address three questions about the Avastin hearing. First, how are the assumptions of bureaucracy—particularly assumptions about procedure and facticity—expressed rhetorically in the Avastin hearing? Second, what do these elements of bureaucratic rhetoric tell us about the purposes and audiences of bureaucracy? And third, what are the implications of continued adherence to these bureaucratic assumptions and rhetorics for the public, the regulatory agency itself, and the scientific and medical establishments over which the agency has such far-reaching power? To answer these questions, I will offer an in-depth study of the Avastin hearing as a case study of the assumptions and rhetorics of bureaucratic approaches to public health and medicine. Then, I will broaden the scope in the concluding chapter to address the potential implications of my findings—particularly the implications of bureaucracy's continued adherence to the assumption that there is such a thing as “the science” to be found in every question of health and medicine, and that the achievement of facticity for a singular version of “the science” must be the basis of all medical and health decisions.

Dramatis Personae

Before delving into a discussion of the literature and theory behind this project, it will be helpful to describe the persons and groups involved in the hearing. While the FDA is a singular unit within the government, it is also made up of a number of committees, groups, and interest areas. The two FDA groups primarily involved in the Avastin hearing are CDER, the Center for Drug Evaluation and Research, and ODAC, the Oncologic Drugs Advisory Committee. CDER is an internal committee, made up of FDA employees who make determinations about the safety and efficacy of drugs based on the thousands of pages of data submitted by pharmaceutical companies and other stake-holders. ODAC, on the other hand, is what is called an external advisory committee. Made up of “outsiders,” not FDA employees, external advisory committees provide guidance to CDER and other FDA committees in particular areas of expertise. In ODAC’s case, the members provide guidance to CDER specifically on oncological drugs. Chapter 4 will provide more background on the relationship between the internal and external committees and call into question any strong distinction between the two in terms of their role in supporting the FDA. Moreover, it is of interest—and was of interest to the speakers at the hearing—that no members of the ODAC committee convened at the hearing were specialists in breast cancer, and all but one had previously already voted against Avastin as a breast cancer drug at least once. The role of this prior commitment in their decision at the hearing is also addressed in Chapter 4.

The other “party” to the hearing is Genentech, the pharmaceutical company that developed Avastin and conducted all of the clinical trials at issue (these are named E-2100, AVADO, and RIBBON 1). This project will not address Genentech’s rhetoric in

detail, as the focus is on the FDA speakers and their interactions with the public speakers. It is important to note, though, that however Genentech may represent itself as a champion of breast cancer patients, and however much the company did, in fact, press the FDA to allow public speakers at the hearing (the public's testimony being almost exclusively favorable to Genentech), it is in Genentech's best long-term interest to remain on friendly terms with the FDA and to "speak the FDA's language." Avastin is just one of Genentech's many pharmaceuticals, and the breast cancer indication is just one of the indications for which Genentech has sought the FDA's approval for Avastin. Whatever the outcome of this hearing, Genentech will need to petition the FDA in the future and will need to do so, not in terms of patient well-being or choice, but in terms of the kinds of scientific evidence the FDA accepts¹. Thus, while this project will not address Genentech in detail, future work on the company's role in the hearing will almost certainly reveal a much stronger rhetorical resemblance between Genentech and the FDA than between Genentech and the patients, despite Genentech's occasional appearance of siding with the patients.

Finally, the other group present at the hearing is the group of public speakers, almost all patients and family members of patients, although a few doctors appear as well. They are considered "nonparties" to the hearing, are literally placed behind a half-wall at the back of the hearing room, are given 3-minute time limits for speaking, and are

¹ Moreover, corporations have much the same tendency toward quantification as regulatory bureaucracies, both because they are themselves bureaucratic institutions to one degree or another, and also because, as Judt (2010) puts it, "markets have a natural disposition to favor needs and wants that can be reduced to commercial criteria or economic measurement. If you can sell it or buy it, then it is quantifiable and we can assess its contribution to (quantitative) measures of collective well-being" (p. 169). Again, the relationship between Genentech's rhetoric and the FDA's will not be a focus of this project, but it suggests a potentially very fruitful future extension to this work.

kept to those time limits with an automated light system that moves to yellow, then red. The microphone is simply cut off when the light turns red, and the next speaker is called. Neither the FDA nor Genentech ever addresses the public speakers or their arguments or claims. The public speakers sit behind the railing for most of the 2-day hearing, essentially ignored, as the bureaucracy and the pharmaceutical company—and the “external” advisory committee—debate “the science” among themselves.

Regulatory Bureaucracy and the Rhetoric of Science

As I will argue below, analyses of bureaucratic rhetorics could enter a number of conversations currently being engaged in within the rhetorical-studies community. Specifically, the identification of differences between political and bureaucratic rhetorics has potentially significant value for the study of political rhetorics and for the study of the contexts of and pressures on rhetorical strategy more broadly. However, this project will focus specifically on the role of scientific rhetoric in the making of decisions in what I will refer to as science-based regulatory bureaucracies. Science-based regulatory bureaucracies (and these make up the majority of American bureaucratic government institutions) draw upon the cultural power of scientific argument to justify their own decisions, as well as the processes by which those decisions are made. As such, these institutions exist at the intersection of what rhetoricians of science have dealt with as the “is-ought” dichotomy: the understanding that science can make claims about what *is*, but that it cannot make decisions about what *ought to be* done. Science-based regulatory bureaucracies, because their mission is to use science to create rules or pronouncements about what citizens are or should be allowed to do, sit precisely at the intersection of “is” and “ought.” Essentially, they are institutions for the translation of the “is” of science

into the “ought” of regulation. Thus, they offer significant potential insights into how this translation occurs, as well as texts rhetoricians can study to understand the potential effects of extracting “ought” statements from the “is” claims of scientific research.

As Zerbe (2007) put it, “Every day, using discourses of scientific research for support, policymakers reach conclusions about who may or may not (or who should or should not) perform certain actions.” These decisions, he claims, are made not on the basis of science per se, but “on the basis of someone’s interpretation of scientific discourse” (p. 4). In other words, the translation from “is” to “ought” is one of interpretation, implying both that the move to regulatory statements is a move outside of science and into a more subjective realm, and also that there is more room for debate of such interpretations than of the science itself. Wynne (2011) makes a similar claim in his discussion of the public debate around the Windscale nuclear facility in the U.K. “Strictly speaking,” he writes, “the Windscale decision was beyond our rational capability.” As a result, scientists and policymakers had to create the appearance of a pure and unquestionable scientific basis for the decisions while in fact making the decision based upon beliefs and interpretations: the decision required the policymakers to “*transform*” the scientific facts at issue (p. 36). As he puts it, this process requires ceremonies of control “as the contradiction develops between belief and experience” (p. 37). Finally, Fahnestock (1986) makes a similar assumption in her claim that, in moving out of the lab and into the public sphere, scientific rhetoric moves from forensic (debating facts) to epideictic (ceremonial celebration of facts). In other words, she also assumes that scientific rhetoric that occurs within the closed world of science deals with “what is,” while political or public applications or discussions of those already-constructed facts

become questions of “what should be” (in her case, she claims that in their epideictic nature, public expressions of science essentially argue that science “should be” lauded and revered).

What all of these statements of the is-ought dichotomy assume is that some kind of transformation of “the facts” must occur between the world of science (the arena of debate about what is) and the public sphere (the arena of debate about what should be done with or about science or policy). As Wynne (2011) argues, “public decisions inevitably entail ritual to patch over inconsistencies between claims of choice and control, and realities of prior commitment and arbitrariness” (36). In other words, his claim is that the move from “is” to “ought” requires a shift from the uncertainties, the ambiguities, and the contingencies of science (as well as the “realities,” as he puts it, of external and internal commitments, conflicts of interest, and other influences on the scientists’ not-necessarily-pure explorations of “what is”) to an appearance of control and certainty in the public sphere. This is necessary, he argues, because making decisions about what ought to be done on the basis of science requires the appearance of a certainty in the science. In other words, the “is” itself is reconstructed in the moment in which it is used to justify an “ought.”

My project enters this ongoing discussion about the is-to-ought transformation between science and public decision making in three ways: by offering an analysis of a science-based regulatory agency as one instance of such a transformation; by examining the ways in which the “is” is constructed and made to appear certain; and by offering a rhetorical analysis of a specific moment in which such an “is” is constructed in order to demonstrate some of the methods by which that transformation occurs. In order to do so,

I will begin by discussing in the rest of this chapter some of the ways in which bureaucracy can be understood rhetorically and the reasons for a specifically rhetorical approach to the construction of certainty in the moment of the “is-ought” transformation.

Bureaucracy as Context

In 1997, Dilip Gaonkar criticized John Angus Campbell, among others in the growing rhetoric of science community, for his reliance on “the model of intentional persuasion” in his studies of scientific writers and speakers (p. 50). Campbell, like many others in rhetorical theory and especially rhetoric of science, placed too much emphasis on the speaking agent as an explanatory construct; for example, Campbell “refuse[d] to yield the image of Darwin,” Campbell’s most common subject, “as the master rhetorician who unfailingly imposed his discursive will” (p. 52). The problem, Gaonkar argued, is “the reading strategy that connects certain textual features to their context of constraints and resources through the agency of the author/speaker” as though that agency were both the primary and the determinant force in constructing rhetoric (p. 53). Gaonkar did give Campbell credit for more recent scholarship in which Campbell had moved toward an “intertextual reading” that decentered Darwin as an agent (p. 60), but he then called for even greater focus on the contextual, intertextual, historical, and other constraints that were at least as important in determining the shape and content of scientific texts.

Gaonkar was certainly not alone in making this critique of rhetorical theory as too invested in individual agency, nor in calling for the placing of scientific rhetoric in the disciplinary, cultural, and historical contexts in which it was constructed. And that call has been heeded (and, to be fair, had begun to be addressed before Gaonkar leveled his critique in 1997). Genre theorists working with scientific texts—Charles Bazerman,

Carol Berkenkotter and Thomas Huckin, John Swales, and Alan Gross, among many others—have argued for the constraining effects of both genre histories and genre conventions on scientific writers. Others have drawn on sociological studies of science (such as those conducted by Thomas Kuhn and Bruno Latour) to place scientific rhetoric in the context of the social and community goals of scientists. Greg Myers, for example, argued that the final form of any scientific text is determined in large part by the social interactions of scientists during the process of its construction. More recently, James Wynn has reconstructed the social and community constraints that drove the rhetorical arguments for mathematical approaches to biology in the 19th century. A collection of scholars from a variety of scholarly backgrounds (Selzer, 1993) considered the impact of reading styles and interpretive lenses on the apparent meanings and functions of scientific rhetoric in *Understanding Scientific Prose*. The specific work Gaonkar praised Campbell for, the analysis of the effects of intertextual forces on scientific rhetoric, has been carried further, especially by Leah Ceccarelli (2001). Ceccarelli specifically identifies the ways in which successful cross-disciplinary texts in the sciences (those that are identified by scientists themselves as effectively crossing disciplinary boundaries to promote new kinds of syntheses) draw on the rhetorical strategies of a variety of texts from multiple disciplines. She identifies particularly the ways that the persuasive strategies of the most successful texts in a given discipline are also used by successful outsiders when speaking to that discipline.

Finally, scientific rhetoric has been studied in the context of its move outside the academy, including so-called “popularization” studies like Jeanne Fahnestock’s (1986) analysis of popularizations as epideictic, as well as studies of the roles of scientific

rhetoric in public forums, as in Lisa Keranen's (2010) analysis of identity construction in breast cancer research. In short, these and many other scholars have very effectively addressed the early critiques of rhetoric of science as epideictic and overly-reverent toward individual scientists as "master" rhetoricians, moving toward offering analyses that deal increasingly with the complexities and nuances of the relationships between individual rhetors, their texts and the larger-scale constraints on those texts.

However, one important aspect of the context of modern scientific rhetoric has remained almost completely unexamined: bureaucracy, and specifically the role of bureaucratic forms of institutional life in constraining what is, and what can be, said by scientific rhetors. This is an incredible oversight, given the powerful and wide-ranging influence of bureaucracy in modern science. Nearly all funding for original research is determined by bureaucracies, whether governmental or corporate, meaning that bureaucratic rhetorics determine the direction and distribution of scientific progress in almost all areas of study. At the same time, most scientists work in bureaucratic institutions, performing their research either in university or industry settings and funding, publishing, and teaching under the aegis of those institutions. Scientists and clinicians are themselves highly aware of the role of bureaucracy and have begun to systematically study the overwhelming effects of bureaucracy on research. *EMBO Reports*, for example (a publication of the European Molecular Biology Organization), published an article in 2010 arguing that "creeping bureaucracy" is often a "burden" for researchers, since "most research, as well as universities and research institutes, is now funded by public agencies using taxpayers' money" and thus distributed, monitored, and often owned by bureaucratic organizations (Wolinsky, p. 664). Similarly, a 2005 article

in *Nature* argued that, as its title proclaimed, the “Main effect of bureaucracy is to reduce productivity” (Moss, 2005).

However, the potential problems with bureaucratic control of scientific and medical research, as I will argue here, go beyond the effects of increased paperwork on scientific productivity. Rather, bureaucracy requires an adherence to proceduralism that severely limits what research can be conducted, how it can be conducted, and how findings can be presented and justified. As a result, bureaucratic oversight often leads scientific and medical researchers themselves to engage in the reductive rhetoric of facticity alluded to in the opening section as representative of bureaucracies.

Two major theorists have in fact called for or implied a need for a rhetoric of bureaucracy.² Kenneth Burke (1969) first indicated the potential for a rhetoric of bureaucracy in his studies of the novels of Franz Kafka and of the administrative rhetoric of Machiavelli. While he makes no sustained or explicit call for a rhetoric of bureaucracy, he lauds Kafka for “delving into the mystery of bureaucracy and the rhetoric that goes with it” (p. 118), then later claims that Machiavelli’s *The Prince* can be read as a “manual of ‘administrative rhetoric’” (p. 164), a type of rhetoric which is not fully fleshed out nor wholly synonymous with the bureaucratic, but which indicates Burke’s

² It is worth noting that the phrase “rhetoric of bureaucracy” has also appeared in the work of other disciplines, especially political science; however, this work consistently uses “rhetoric” to mean language generally, and most often to mean language somehow in opposition to “reality,” as in Katherine C. Naff and John Crum’s (2002) “The President and Representative Bureaucracy: Rhetoric and Reality,” which contrasts politicians’ statements about their desire for a “representative bureaucracy” with the “reality” of their actual policies. Such pieces do not theorize rhetoric, do not use a concept of rhetoric consistent with rhetorical theory, and do not offer any concept of a “bureaucratic rhetoric”—yet unfortunately, they remain the most common instances of the study of “rhetoric” and “bureaucracy.”

interest in the rhetorics of the institutions that “administer” public life, including the bureaucratic.

Bruno Latour and Stephen Woolgar (1979), by contrast, did make an explicit call for a rhetoric of bureaucracy. They argued that the bureaucrat was more than a type; rather, the bureaucrat was *the* type of the modern state, both typifying the work of the state and productive of its identifying characteristics. They also pointed out the importance of bureaucratic rhetoric for the study of scientific work specifically. In “following” scientists and their work “through society” (as their subtitle claims), Latour and Woolgar argue that if one intends to follow scientific texts and fully understand their effects outside the academy, one must study bureaucracy. They offer three reasons. First, bureaucrats are the representative type of modern human, and especially of modern scientist: “believing more the *nth* order paper form than common sense,” they argue, “is a feature of astronomers, economists, bankers” and of all those who work in the knowledge-producing centers typical of the modern Western state (p. 255). Second, the rhetoric of bureaucrats is important not only because it is typical, but because it is a concrete (and paper-and-text-rich) trail by which to follow the effects of science in society: “Understanding the bearing of bacteriology on ‘society’ might be a difficult task,” they admit in one example,” but following in how many legal, administrative and financial operations bacteriology has been enrolled is feasible: just follow the trail” (p. 255). Finally, they argue that our modern society is itself produced by bureaucratic agencies: “a stable state of society,” they write, “is produced by the multifarious administrative sciences” (p. 256).

As much as half a century ago, then, the concept and importance of a “rhetoric of bureaucracy” was available to rhetorical scholars and its importance demonstrated. Why, then, has so little work been done in that direction? One possibility is the claim, made mostly by organizational psychologists, that modern institutions are somehow “post-bureaucratic.” However, this is not the primary or even a central reason, first because it does not reduce the need for a rhetoric that makes sense of those institutions that are bureaucratic, and also and more importantly in light of scientists’ own perception that their work is, in fact, organized by bureaucratic, not “postbureaucratic,” organizations. Latour and Woolgar offered another possible reason: the scorn many citizens and scholars feel for bureaucrats and the perception that they are simply paper-pushers with no autonomy and therefore no rhetorical interest. Once we take the study of science’s work in society to its end, they argue, “we might end up studying the most despised of all the aspects of technoscience: the paper-shufflers, the red-tape worms, the bureaucrats” (p. 255). Certainly, Burke’s reliance on Franz Kafka’s work as presenting a representative picture of bureaucrats would not lead him to a positive image of their work.

Yet another possibility is that the texts, transcripts, and conversations that make up truly bureaucratic institutions are often not available to scholars; companies maintain secrecy around their deliberations as much as possible, and until recently, the government has done the same. For example, until the mid-1990s, both the content of packaged foods and the processes by which those contents were approved by companies and the FDA were essentially invisible to Americans. It was possible to request, through certain Freedom of Information Act regulations, documents from the FDA, but anything deemed “confidential” to the company was not available. In addition, actually accessing the

documents, which often required requesting and being allotted research time in a library of millions of pages of documents, was often prohibitively difficult before the advent of the internet.

These, however, are not the primary reasons for the relative neglect of bureaucratic rhetorics. Rather, the culprit has been the assumption that, even if they are not synonymous, bureaucracy and politics are covered under the same theories—that bureaucratic rhetoric is a kind of subset of political rhetoric. Burke himself worked from this assumption. In his argument that administration is rhetorical (that it “makes appeals,” in his terms), he writes, “This point is particularly necessary when we turn to the rhetoric of bureaucracy, as when a political party bids for favor by passing measures popular with large blocs of voters” (p. 161). A direct and wholly inclusive synonymy is assumed here between politics and bureaucracy; the example of “bureaucratic” rhetoric he offers is of political parties pandering to their constituents.

Others (mostly in other fields, since our own field has offered a proliferation of studies of political rhetoric alongside a near nonexistence of similar studies of bureaucratic rhetoric) have made the same conflation of bureaucracy with politics. Craig R. Smith’s (1999) “The Campaign to Repeal the Fairness Doctrine,” one of the very few studies to address rhetoric and bureaucracy together at all, is typical of the ways in which the distinction between bureaucracy and politics is at best under-theorized. Smith claims that he will reveal “the role public address plays in a bureaucratic republic” (p. 481), but in fact, he never addresses what, precisely, is important about the “bureaucratic” nature of the republic. Instead, he proceeds to offer a description of the types of speeches made by politicians and other advocates during multiple attempts to garner political and public

support for the repeal of the Fairness Doctrine. While he does describe, as part of that, a series of Congressional hearings (which certainly might fall under the category of “bureaucracy”), he does not theorize the effect that the specifically bureaucratic nature of such hearings has on what is or can be said at them. Rather, he simply lists the kinds of speakers present and the types of arguments made (and that very briefly). He then goes on to describe the ways that he and his political allies went to “seek the endorsements of prominent professional and academic groups” (p. 485) in order to garner diverse support, a typical element of *political* rhetorical maneuvering that is not in any meaningful way bureaucratic.

Bureaucracy vs. Politics

That bureaucracy is not simply a subset of politics—that in fact bureaucracy and politics are in many ways incompatible, despite all their interpenetration in the modern state—is clear from Max Weber’s descriptions of the clashes between democratic and bureaucratic types of authority³. Weber, identified by Anthony Giddens as one of three early sociologists who not only defined sociology but helped define what it means to “be modern,” took bureaucracy as his key term; for him, bureaucracy was a new kind of authority, an authority based not on tradition or on the “charisma” of individuals, but on “calculable rules” and “without regard for persons” (Weber, 1978, p. 192). In asking under what conditions “people subjectively view commands as legitimate and obey them” (p. 173), Weber argued that such legitimacy—what he called “legitimate

³ Obviously, democracy is not the only kind of politics. However, as this project is interested in bureaucracy in the modern Western state, and specifically in the United States, and also since for rhetoricians of politics since Aristotle “politics” has been synonymous with “democracy,” I will focus on democracy here. Potential implications for other forms of political life would be an interesting avenue for exploration in future research.

domination” or authority—assumed three “pure types”: authority based on tradition, or “an established belief in the sanctity of immemorial traditions”; authority based on charisma, or “devotion to the exceptional sanctity, heroism or exemplary character of an individual person”; and authority based on rationality, or “a belief in the legality of enacted orders and the right of those elevated to authority under such order to issue commands” (p. 192)⁴. American democracy, at least ideally, draws its legitimacy from the first type, with the “immemorial traditions” it is based on being the rights and responsibilities laid out in the *Declaration of Independence* and other founding documents. According to Weber, the third type—the rational or bureaucratic form of authority—overwhelmed and replaced the other two and has come to typify the modern state.

That the basis of the legitimacy of bureaucratic authority not only differs from but fundamentally conflicts with the basis of legitimacy of democratic authority is clear from Weber’s constant contrasting of the two. Bureaucracy, he argued, “both in business offices and in public service, promotes the rise of a specific status group,” appointed by superiors on the basis of technical skills and institutional knowledge, not elected by the governed. It is “precisely against this unavoidable status character of bureaucracy that ‘democracy’ reacts in striving to put the election of officials for short terms in place of the appointment of officials and to substitute the recall of officials by referendum for a regulated disciplinary procedure” (p. 202). In other words, bureaucracies arise in response to a need caused by the inherent instability of democratic administration, the “growing complexity of the administrative tasks” in the modern state, and “the sheer

⁴ It is interesting—although not addressed in this study—that Weber’s three types of legitimacy are so closely analogous to the rhetorical concepts of *ethos*, *pathos*, and *logos*.

expansion of their scope,” all of which favor “the probability of the rise of a special, perennial social form for administrative purposes” (p. 188)—what has been called the permanent government. As they grow, however, these bureaucracies also come into conflict with the democratic ideals that caused the need for them in the first place. “‘Democracy’ as such,” as Weber puts it, “is opposed to the ‘rule’ of bureaucracy, in spite and perhaps because of its unavoidable yet unintended promotion of bureaucratization” (p. 205) because democracy explicitly relies on “prevention of the development of a closed status group of officials in the interest of a universal accessibility of office” and “minimization of the authority of officialdom in the interest of expanding the sphere of influence of ‘public opinion’” (p. 210)⁵. Thus, while it is the nature of democracy to create bureaucracies to take charge of growing administrative complexities, nonetheless, democracy continues to conflict with the administrative institutions it creates, especially as they grow in power.

Others besides Weber have noted the inherent tension between bureaucracy and democracy and, specifically, the difference in their forms of legitimacy. John Marini (1992), in his discussion of the competing roles of politics and bureaucracy in Watergate, reaffirms that the basis of democracy is “legitimacy by election,” and that since Watergate, “executive leadership responsive to the will of a national majority has been weakened; bureaucratic or centralized administrative rule [...] has become almost institutionalized” (p. 2). The implication is that as such bureaucratic administrative rule

⁵ Obviously, this is an idealization of democracy that does not take into account, for example, the influence of money or the so-called “special interests” in many modern Western democracies (see for example Wolin, 2010, on “managed democracy”). However, this idealization does not affect the project outlined here; it is precisely the *political* aspects of democracy (ideal and not so ideal) that differentiate it from bureaucracy.

grows, democracy—based on “legitimacy by election”—weakens. Similarly, John Ferejohn and Charles Shipan (1990) suggest that although Congress and other elected bodies, and the statutes they construct, “serve as constraints on what bureaucrats can do,” nonetheless, a bureaucracy can enact rules outside the bounds of those statutes by “embarking on rule-makings, establishing internal quasijudicial practices or precedents, or by allocating resources internally” (p. 3). Clearly, although bureaucracy and politics interact constantly and constrain one another to some degree, nonetheless, their sources of authority and legitimacy are fundamentally at odds. As a result, their rhetorics are likely to be very different, perhaps incompatible—not synonymous or mutually inclusive.

The difference is captured by Donald C. Langevoort’s (1990) characterization of the workings of the bureaucracy in the Securities and Exchange Commission (SEC). He argues that previous scholars of the SEC (and other bureaucracies) have focused too much on “interests.” According to Langevoort, the predominant theory about government workings has been the “public choice theory,” which assumes that “policy will usually reflect an accommodation or compromise among various competing interests” (largely outside the government itself) and that “the bottom line is always responsiveness to those external interests” (p. 529). While politics does work in this way, Langevoort strongly denies that a responsiveness to external interests characterizes bureaucracy. A “vast body of research on organizational behavior,” he claims, “argues that the activity of a bureaucracy is not characterized by a high degree of either sensitivity or responsiveness to external stimuli. Instead, typical behavior is more aptly described as inner-directed” (p. 529). He goes on to clarify this “inner-directedness” as a tendency to “displace stated goals with more self-serving institutional ones” (p. 529),

goals that support the propagation and continuation of internal rules and procedures over the achievement of constituent-identified, political, or democratic goals.

Defining Bureaucracy

What, then, are the characteristics of bureaucracy that drive its inner-directed rhetoric, and what are the features of that rhetoric? I will address the features of the rhetoric much more fully in the next chapter, but for now let us identify and define the characteristic traits of bureaucracy—not only those that differentiate it from politics and democracy, but those that drive its typical forms of rhetorical action. Although, like Burke, Weber does identify hierarchy as one of the features of bureaucracy, this feature neither differentiates bureaucracy from other forms of authority nor helps us understand the particular workings of bureaucratic authority. Although he does not label them as such, Weber’s detailed descriptions of bureaucratic structures suggest—and I will argue—that five features in combination define the modern bureaucracy. These are rule-based action, organization around roles in which individuals are interchangeable, reliance on “the record,” reliance on expert rather than popular opinion (especially for the justification of rules), and an homogenization of individuals. Let us examine these five characteristics in more detail.

The first characteristic Weber identifies is management by “*general rules*, which are more or less stable, more or less exhaustive, and which can be learned” (p. 196). This differentiates bureaucracy from democracy more completely than any of its other features because in a bureaucracy, rules override the interests of individuals, constituents, the public, and politicians—in fact override all other considerations. As Weber puts it, “Bureaucracy develops the more perfectly, the more it is ‘dehumanized,’ the more

completely it succeeds in eliminating from official business love, hatred, and all purely personal, irrational, and emotional elements” and applies rules that are “calculable” and therefore consistent (p. 200). This consistency is extremely important: when a decision is to be made, it is made on the basis of the rules and procedures that have been established, not on the basis of individual cases or the desires of any group (even those being governed or those making the decision).

The basis of these rules is their assumed rationality: “in principle a system of rationally debatable ‘reasons’ stands behind every act of bureaucratic administration” (p. 201). Paradoxically, however, the rules need not be consistent from one to another, explicitly stated or codified, or well-defined; as Langevoort argues, it is in fact in the bureaucracy’s interest to have a “disinclination to adopt or endorse bright-line rules, notwithstanding the obvious value of such an approach in promoting planning and reducing the incidence of litigation.” For Langevoort, the question is one of jurisdiction and interpretive power: bureaucracies embrace changeable rules because they are “jealously intent on preserving the larger degree of discretion,” even “after the fact” (p. 531). By employing rules that are ambiguous, but at the same time requiring that such rules be followed consistently in every instance, bureaucracies thus maintain a “special technical expertise” (Weber, 1978, p. 196) and preserve their ability to both insist on the consistent application of rules and to interpret those rules as they see fit to promote their own internal interests. For Langevoort, those interests grow, over time, to be more and more conservative as the purposes of those rules becomes their own reproduction and “institutional [...] self-preservation” (p. 530).

The rules become even more important—and even more involved in their own self-replication—in light of the interchangeability of actors in a bureaucracy. In this kind of administration:

submission does not rest upon the belief and devotion to charismatically gifted persons, like prophets and heroes, or upon sacred tradition, or upon piety toward a personal lord and master who is defined by an ordered tradition, or upon piety toward the possible incumbents of office fiefs and office prebends who are legitimized in their own right through privilege and conferment. Rather, submission under legal authority [another term he sometimes uses for bureaucracy] is based upon the *impersonal* bond to the generally defined and functional ‘duty of office.’ (Weber, 1978, p.198)

Or again: “It is decisive for the modern loyalty to an office that, in the pure type, it does not establish a relationship to a *person*, like the vassal’s or disciple’s faith under feudal or patrimonial authority, but rather is devoted to *impersonal and functional* purposes” (p. 202). In short, authority derives from the office—the role—not from the person; to use a business example, if a position called “Vice President of Sales” exists at a company, then whoever fills that role receives the deference due to the role, wields the authority incumbent in the role, and is meant to be substantially equivalent to all others who have filled the role—and moreover, that Vice President is given these privileges and constraints whatever his or her previous role and only until he or she is moved to fill a new role. The basis of bureaucratic functioning, in other words, is the interchangeability of individuals into and out of predefined roles that carry their own authorities and responsibilities regardless of the person currently fulfilling them.

Langevoort again updates Weber here, adding to Weber’s concept of interchangeability and “duty of office” the practical realities of turnover and jurisdiction. Many bureaucrats fill their positions very briefly, he notes, returning to private businesses or turning their administrative experience to other tasks. As a result, turnover is high. At

the same time, bureaucracies are characterized at least as much by jurisdiction (as Weber himself noted) as by hierarchy, meaning that “some level of consensus among jurisdictions has to be achieved” (Langevoort, 1990, p. 532), even as individuals are changing in and out of roles. The combination of turnover and jurisdictional relationships, Langevoort claims, is a recipe for “conservatism, risk avoidance, ‘turf protection,’ and routine” (p. 529) because as new individuals step into existing roles—and into the middle of ongoing decision-making processes and jurisdictional debates—“consensus is influenced not so much by first-hand experience in earlier negotiations but by some record of the historical result,” as the “invocation” of conventions “becomes a means of demonstrating good faith commitment to institutional goals” over one’s own, as well as adoption of one’s proper role (p. 533). In this way, the interchangeability of individuals into and out of predefined roles, combined with turnover, creates not only role-identification but, perhaps more importantly, a supreme reliance on the established rules and procedures of the organization over and above individual or case-by-case decision making.

The third defining characteristic of bureaucracy is reliance on “the record,” or the collection of formal documents that both create and reflect the bureaucracy’s (often ambiguous) rules. The “bureau” or “file” that originally led to the word “bureaucracy” is just this collection of documents, the precedent by which new occupiers of institutional roles can learn, then signal their adherence to, the bureaucracy’s purposes and goals. While Weber places less emphasis on the record than on “calculable rules” and impersonality, he does argue that the “management of the modern office is based upon written documents (the ‘files’)” and that the function or effect of the record is twofold.

First, it connects the employees of the bureaucracy with their work. “The body of officials working in an agency along with the respective apparatus of material implements and the files,” Weber writes, “makes up a *bureau*” (p. 195); the employees are thus both equal to and equivalent with the files, making up parts of the bureau or “office” itself and replicating its rules. Second, the file, as one part of the management of the office through rules, “separates the bureau from the private domicile of the official and, in general, segregates official activity from the sphere of private life” (p. 195).

Both of these functions of “the file” reinforce the role-basis and interchangeability of bureaucratic work; the more the bureaucrat at work is “segregated” from her private life—that is, from her other identities and communities—the more she can align herself with the institution’s goals, even if they conflict with the principles she and her community carry outside the institution. As Weber put it, if a superior in the bureaucracy asks her to execute a “directive,” “it is [the bureaucrat’s] duty and even [her] honor to carry it out as if it corresponded to [her] innermost conviction, and to demonstrate in this fashion that [her] sense of duty stands above [her] personal preference”—to show that she is committed, at least during her time in the office, to her role in the bureaucracy above her role in any other community (p. 203). The bureaucrat’s *equivalence with the file*, her position as just another means of propagating the institution’s rules, also reinforces her role-affiliation by committing her to be a carrier rather than an originator, a bureaucrat who enforces rules created by others (rather than, for example, a politician who creates and argues for new legislation).

Langevoort also indicates the centrality of the record in the running of a bureaucracy and its promotion of role-affiliation. Because decision making is based on

“the record,” “the expression of an idea comes to take on a life of its own” while “the turnover of key personnel” means that these expressions, the written record, come to create “the *perception* of the past” on which new decisions are based (p. 533).

Altogether, then, with employees (who are interchangeable into and out of predefined roles and experience regular turnover) acting as equivalents to the record in their zeal to demonstrate their “good faith commitment” to the institution’s goals, and with all such decisions being based on a set of rules that are simultaneously consistently applied and largely ambiguous (or clear only to insiders—what Langevoort calls “an impenetrable admixture of highly technical [...] law and unwritten lore” (p. 531)), the bureaucracy encourages role-affiliation and the enactment of institutional rules *through* a predefined role over all other forms of action, as well as “convention rather than analysis” (p. 534). In the Avastin hearing, as we will see, this plays out in the very different rhetorical strategies of the doctors (mostly oncologists) of the ODAC panel as opposed to the doctors (mostly oncologists) who speak as members of the public. Their roles in the hearing and in the bureaucracy, rather than their membership in the community of medical practitioners or oncologists, drives their rhetorical patterns.

Taken together, these characteristics require the other two: reliance on expert opinion and the homogenization of individuals. Expertise of two kinds, working together, drives the “record” and the set of institutional rules: specialization in a field that provides the imprimatur of “rationality” to the institution’s rule-set, and specialization in that rule-set itself, in the workings of the bureaucracy. Thus, the experts who drive modern bureaucracy are doubly expert, doubly insiders; they already possess specialized knowledge from an outside field (such as law or medicine), and they come to possess

specialized knowledge of the arcane and ambiguous rules of the organization. Weber notes this quality of bureaucracy only in passing at first, claiming that “[o]ffice management, at least all specialized office management—and such management is distinctly modern—usually presupposes thorough training in a field of specialization” (p. 196). Later, though, he goes on to explain why such specialization is necessary. Bureaucracy, he argues, is “fundamentally domination through *knowledge*. This is the feature of it which makes it specifically rational” (as opposed to the “traditional” and “charismatic” types of domination) (p. 204). In other words, specialization in a technical field of expertise operates as domination by providing the rules of the institution with the stamp of rationality, which provides a sense both of objectivity and of value. The second type of expertise works in tandem with the first. In addition to specialized knowledge of a “rational” field of inquiry,

bureaucratic organizations, or the holders of power who make use of them, have the tendency to increase their power still further by the knowledge growing out of experience in the service. For they acquire through the conduct of office a special knowledge of the facts and have available a store of documentary material peculiar to themselves. (p. 204)

Not only does this claim demonstrate the close relationship between “the record” and the special expertise of the bureaucrat, but it suggests the interrelationship—a *circular* interrelationship, I will argue—between the two types of expertise. The outside or academic expertise (that is, the knowledge of law or science or whatever discipline applies to a particular agency) constructs a (sense of) rationality by which to validate the rules of the institution, which in turn are truly known (in all their paradoxically ambiguity and consistency) only by those same experts, who then both draw their own validity from

their knowledge of the record and simultaneously grant validity *to* that record by their expert status.

The validity of these rules is further legitimized by the homogenization of individuals. Inside the bureaucracy, individuals are homogenous in the sense that they are interchangeable into and out of predefined roles (anyone with certain certified qualifications can fill any slot with a particular description), while individuals outside the bureaucracy are even further homogenized by, and in the eyes of, the bureaucracy. Indeed, for “rational” rule-based authority to be in any way legitimate, it must be the case that all the individuals to be governed are equivalent. This concept has applied to modern statecraft (and to public health, which is the focus of the case study in this project) since at least the middle of the 18th century, when the French philosopher Ambrose Condorcet, in constructing his concept of “social mathematics,” came to believe that “society was made up of homogenous individuals all born equal under the law” (Porter, 1999, p. 66). This homogeneity made it possible, according to Porter, “to discover the mathematical laws which governed the social mechanism” (p. 66)—that is, made it possible not only to discover rules underlying social life but also to turn around and apply such rules equally to all the individuals being governed.

Weber makes very clear the difference between such homogenization and the democratic concept in “the ‘equal rights’ of the governed,” which would lead away from “the development of a closed status group of officials” like a bureaucracy (p. 210). In contrast to such a democratic ideal, the homogenization of individuals means “the *leveling of the governed* in the face of the governing and bureaucratically articulated group” (p. 210, emphasis in original). In bureaucratic governance, then, the individuals

being governed are neither involved in the creation of rules (since they are not experts in either sense), nor do they have discretion in applying those rules (since they are *equivalent* to one another, not *equal* to the bureaucrats in the sense of having the right of interpretation). In this, as in the other characteristics described here, bureaucracy is fundamentally different from—often deeply opposed to—politics, particularly democracy. As I will demonstrate in the analysis chapters, this difference is not only expressed through the rhetoric used by bureaucrats in promoting the institution’s self-perpetuating goals, but itself becomes a subject of contention in interactions between the bureaucracy and those it seeks to administer.

Why a “Rhetoric” of Bureaucracy?

Given that Weber outlined the characteristics (and characteristic types of action) of the modern bureaucracy nearly a century ago, and did so fully enough that while he has been updated and interpreted, his understanding of bureaucracy still defines the sociological approach to its study—and given also that sociologists have devoted considerable scholarship already to characterizing and understanding the working of bureaucracy—what can a *rhetoric* of bureaucracy add? In order to answer this question, it makes sense to draw upon the work of the early (and some more recent) rhetoricians of science, who have had to answer the same types of questions in response to sustained criticism of their endeavor. Many critics argued that science itself was not amenable to rhetorical analysis, but that critique can be dispensed with in a study of bureaucracy, which in addition to having already been glancingly studied by rhetoricians as part of “politics,” is also made up, as Weber himself said, of documents. Any institution whose defining characteristic is the construction and enactment of the rules of its own

functioning through a documentary record is surely amenable to all types of textual analysis, including the rhetorical. The other sustained critique of rhetoric of science, however, that sociologists and historians of science had already provided the “contextual” and “social” understandings of scientific work that rhetoric claimed to offer, and thus a rhetoric of science was derivative or redundant, could well be applied to a rhetoric of bureaucracy. The responses of the rhetoricians of science to their critics can equally be applied in claiming that a rhetoric of bureaucracy adds significantly to the existing sociology of bureaucracy.

On the most basic level, the early rhetoricians of science argued for a rhetorical analysis of science purely on the basis that more layers of analysis are in themselves better. As Alan Gross (2006) argued in *Starring the Text: The Place of Rhetoric in Science Studies*, “rhetorical analysis, like sociological, historical, or philosophical analysis, is limited in scope; indeed, it is such limitations that provide the focus that gives disciplines their strength.” Thus, bringing together a number of different analyses, including the rhetorical, “sheds a different and valuable light on the sciences” (p. 21). Jack Selzer (1993) similarly argued for a layering of many methods of analysis in the study of science, writing that “a primary aim of [his edited collection] *Understanding Scientific Prose* is to illustrate—and argue for—a pluralistic range of methods” in interpreting scientific texts (p. 7). Finally, Greg Myers (1990) broadened the argument not only to suggest that text interpretation is simply one more useful analysis among many, but that texts themselves have an advantage as objects of study: “written texts function as evidence” he wrote (p. 7), because to a certain extent “texts hold still” and “texts are portable” (p. 6). However, these broad claims can apply to any textual analysis

or to any new analytical framework, whereas rhetoricians of science also made much more specific claims for the value of rhetoric as an analytical tool based on the particular aspects of texts that rhetoric uncovers. The two that I will focus on are rhetoric's specific interests in the persuasive functions of language and in audience.

The synonymy of "rhetoric" with "persuasion" has certainly been challenged. Kenneth Burke wanted to replace persuasion with "identification," I. A. Richards claimed that the true study of rhetoric was "miscommunication," and Chaim Perelman and Lucie Olbrechts-Tyteca (along with others, including Stephen Toulmin) have tried to make "argumentation" the key term in rhetorical studies. However, "persuasion" not only remains the most commonly used defining term in discussing what rhetorical analysis looks for, but was also the key characteristic of rhetoric to which the early rhetoricians of science pointed to suggest rhetorical analysis's difference from other kinds of textual study. Moreover, the concept of persuasion will be central to the study of bureaucratic rhetoric specifically because, as Weber argued, bureaucracy is a form of authority, meaning that one of its most important functions—perhaps its most important—is its own legitimation. Any argument for the legitimacy of a type or instance of authority is by definition an attempt to persuade. Charles Bazerman (1988) made a similar claim about science, arguing that attempts to persuade others about the truth or validity of a claim is the nature of *both* science and rhetoric: "Persuasion," he wrote, "is at the heart of science, not at the unrespectable fringe." In seeking to find the truth of the natural world, scientific communication "is not that which disowns persuasion, but which persuades in the deepest, most compelling manner" (p. 321). Myers (1990) also linked persuasion and legitimacy, claiming that his primary question was "in what way do texts contribute to

the social authority of science?” (p. 14), and that for the scientific communicators he studied, the purposes of their texts—grant proposals and scientific articles, for example—was to persuade (p. 41). Thus, the authority or legitimacy of science’s claim to reality is based on the persuasiveness of its texts.

Many others have made the same claim, but what is important here is not merely the number of scholars who have linked legitimacy and authority with persuasion, but the aptness of this approach for a study of the rhetoric of bureaucracy. Because a bureaucracy’s primary goal is to achieve its administrative ends—and because it achieves these ends by justifying and arguing for the legitimacy of its own rules and procedures—it is highly amenable to the study of its texts as instances of persuasion. A rhetoric of bureaucracy, in other words, asks how the bureaucracy’s texts persuade others to believe in the legitimacy of the rules being enacted through those texts. (At the same time, this rhetoric is “self-persuasive,” legitimizing the authority of bureaucratic rules and decisions by justifying their validity to the members of the bureaucracy itself.) As Leah Ceccarelli (2001) wrote, although scientists and sociologists had themselves already identified *why* particular texts were effective, they had not analyzed the internal workings of the texts themselves to identify *how* certain features “manifested” themselves in the texts or *how* the texts “worked such a remarkable influence” on other scientists (p. 30). In other words, while a sociological approach (whether to science or to bureaucracy) can offer insights into how an institution is organized or why a text occurred or had influence in that institution, it does not analyze the texts themselves—does not explain how a text’s form *constructs* legitimacy and persuasion.

However, this concept of persuasion does raise another very important question, one that was also central to the argument for a rhetoric of science: *to whom* is the rhetoric addressed? A focus on this question, on the problem of audience or intended audience, has been central to rhetoric since at least Aristotle, who divided rhetoric into three types based on three types of audience (deliberative, forensic, and epideictic) and on a description of which approaches would persuade each type of audience. Perelman and Olbrechts-Tyteca (1969) updated Aristotle's concept in the middle of the 20th century, arguing that a distinction should be made between what they called the "universal" audience and "specialized" audiences. Rhetoric of science has (generally without explicitly saying so) taken up this distinction. Jeanne Fahnestock (1986), for example, argued that research reports were intended for a specialized audience of peers, while "popularizations" were written to a general audience of nonspecialists; she even equated this difference with Aristotle's concept of audiences, suggesting that research reports were forensic while popularizations were epideictic. Ceccarelli (2001) also updated the concept, going even further to establish audience analysis as a near-requisite of rhetoric of science analyses; she claimed that one could not simply analyze a text for the persuasive effects it was intended to have, must not only conduct "a close reading of the text in context to offer hypotheses about how readers might have been invited to respond to the text's appeal," but must also test "these hypotheses through a close reading of contemporary responses" (p. 8). In other words, it was not enough to identify the ways in which an author intended a text to persuade; one also had to figure out whether that persuasion had been achieved, and *for which audiences* it was persuasive.

This type of audience analysis is yet another way in which rhetorical analysis can supplement sociological analysis of bureaucracy, which is focused nearly exclusively on the forms of institutions and not on their effects on the audiences of their texts (this despite the fact that the audiences of their texts are, in one way or another, all the citizens of the modern world). More importantly, though, audience analysis will allow me to answer important questions about how bureaucracies function because identifying *whom* the bureaucratic speakers feel they must persuade helps us identify the purposes and functions of the bureaucracy (whether these are “purposeful” in the sense that the members of the bureaucracy set out to achieve them or, alternately, “functional” in the sense that these outcomes are those that are achieved by bureaucracy, perhaps without clear intention or purpose—or both). This question falls under the larger question, discussed above, about the differences between bureaucracy and politics. Politicians, whose purpose is to promote certain interests, address their speeches and texts to those who have power over them, the electors and those who fund campaigns. Bureaucracies, however, function differently specifically in that they are not elected but appointed; they need not persuade the electors, except to the limited extent that elected officials have indirect power over the budgets and statutes that allow the bureaucracy’s work to continue. Bureaucracies also operate on longer time scales (because they need not stand for reelection) and operate on the basis of set rules whose intent is to eliminate “interests” in the name of objectivity. Who, then, are the audiences of bureaucracy? To whom must a bureaucracy’s claims to legitimacy be persuasive, and in what ways must it persuade those audiences? This will be the second question addressed by the rhetoric of bureaucracy proposed here.

In short, then, the rhetoric of bureaucracy, while drawing heavily on sociological accounts, also supplements them significantly. In the first place, a rhetorical analysis supplements sociology by offering insight into what Ceccarelli (2001) termed “the mechanisms of influence” (p. 30) by which texts actually accomplish the work of the bureaucracy. While sociologists have described the forms and actions of bureaucracy, they have not identified the maneuvers—the largely *textual* maneuvers—by which those forms and actions are both carried out and justified, and this despite the fact that they identify texts (the “record”) as central to bureaucracy’s very existence. Second, a rhetorical analysis of bureaucracy supplements sociological accounts by asking who the audiences of bureaucratic texts are. While sociologists all the way back to Weber have claimed that arguing its own legitimacy is not only important to, but may be the primary function of, a bureaucracy, nonetheless, sociological studies of bureaucracy do not offer the tools necessary to understand *to whom* this legitimacy must be argued, *in what ways* it is constructed in actual texts, and *what effects* bureaucratic rhetoric has not only on the bureaucracy and its audiences, but on the ways writing and rhetoric are done in other fields, especially in science.

Finally, as is implied by the above, the other value of a rhetorical approach to what has so far been a sociological question is the ability of rhetorical analysis to seek out and understand individual cases in detail, rather than social institutions in their “typical” forms. While Weber’s characteristics of bureaucracy surely apply to all bureaucracies, they do not apply evenly or equally. Moreover, most bureaucracies are in no way “pure” (something Weber himself did admit), but make up part of what Michel Callon, Pierre Lascoumes, and Yannick Barthe (2001) call “hybrid forums,” “forums because they are

open spaces where groups can come together to discuss technical options involving the collective, hybrid because the groups involved and the spokespersons claiming to represent them are heterogeneous, including experts, politicians, technicians, and laypersons” (p. 18). Given Weber’s description of bureaucracies as staffed by experts and secretive in maintaining their rules and procedures within an initiate, the functioning of bureaucracies in hybrid forums (in which, for example, politics, scientific expertise, and law may clash yet must all be satisfied in some way in order for action to be taken) is of special interest in *particularizing* the workings of different bureaucracies. Case studies, in other words, can allow us to understand how the typical workings of a bureaucratic institution come into conflict with and accommodate themselves (or do not) to the broader democratic system in which they must operate—and within which they attempt to maintain their own authority and institutional integrity. As Lisa Keranen (2010) puts it, “Because one of the core assumptions of rhetorical perspective is that rhetoric arises from unique constellations of sociohistorical circumstances, its study must attend to the complexion of particular cases” (p. 8). Furthermore, “atypical” cases can be the most enlightening, as Myers (1990) suggests: it is in the conflicts, the unusual cases that do not proceed according to the normal rules of operation, that “one sees social processes that are also at work in other texts, but which are less easily seen when all goes smoothly” (p. 39).

A rhetorical approach to bureaucracy, then, identifies individual cases or instances in which the “normal workings” of a bureaucracy are in conflict with other interests, with the bureaucracy’s own audiences or employees or with outside forces. In these cases, the bureaucracy, which normally runs behind its veil of secrecy and operates on rules that are

largely implicit, finds itself needing to justify and argue for its procedures and rules—an opportune moment for the rhetorician because it offers insights into the bureaucracy’s sense of itself, its audience, its purposes and goals, and the basis of its legitimacy.

This project will apply rhetorical analysis to the FDA hearing on Avastin—a rare moment in which a bureaucracy had to directly confront members of the public and other interested parties and justify the legitimacy of its own rules and procedures. What this analysis will demonstrate is that a bureaucratic rhetoric is truly different from (perhaps even opposed to) a political or democratic rhetoric, and that in order to understand fully the workings and influences of bureaucracy on the lives of all the citizens of the modern world, we must understand not only its structure but also its modes of persuasion—who the bureaucracy feels it is beholden to and must address (and who it feels can be ignored and not addressed), what forms its persuasion takes (and thus on what grounds it feels itself to be legitimate), and most importantly, how a bureaucracy *uses* rhetoric to achieve its most important function, the closed, unquestioned, and standardized application of its own, internally-constructed set of rules and procedures at the cost of all else, even if the “all else” is the very democracy it was created to serve.

Case Study

The company that created Avastin, Genentech Roche (referred to throughout as Genentech) began Phase 1 FDA trials for the drug in 1997. Since Phase 1 involves testing on humans, albeit healthy ones and not “patients,” entering Phase 1 indicates that a drug has already gone through significant chemical analysis and animal testing. When Phase 1 trials showed Avastin not to have significant harmful effects on healthy volunteers, Genentech and the FDA both agreed to pass it on to Phase 2, the first phase in

which the drug is tested on patient populations. Generally small in scale, Phase 2 tests are intended to identify the drug's "efficacy," one of the two key defining terms in the FDA's mission (Phase 1 is designed to test only the other, "safety"). Genentech began Phase 2 trials of Avastin in 1998 and was successful in establishing a base-line of efficacy. Once this was established, Phase 3 trials could begin, in which larger and more diverse patient populations were brought into the studies so that the efficacy and safety of the drug could be more accurately determined—at least, as much as is possible before wide-scale distribution, which can only occur after FDA approval. Genentech originally began Phase 3 trials for Avastin in 2000, but Phase 3 trials are more specifically-targeted than Phase 2. General efficacy is no longer enough, and the drug must be tested in specific populations. Based on earlier tests and predicted outcomes, Genentech performed its initial Phase 3 trials for Avastin in metastatic colorectal cancer populations. That specific use of Avastin for colorectal cancer—in FDA parlance an "indication" for the use of that drug for that particular disease—was approved by the FDA in 2004. After further testing, the drug was approved for a lung cancer indication in 2006.

It was at this point that the approval process for Avastin became complicated. The FDA and Genentech (and patient groups) disagreed about the results of testing, and the stage was set for the case study this project deals with, the 2011 hearing about the drug's indication for metastatic breast cancer. Although Genentech claimed that the outcomes for the lung cancer and breast cancer trials were essentially the same, the FDA disagreed, and in 2007, one year after the lung cancer indication was approved, an FDA advisory committee voted 5-4 against approval of the breast cancer indication. The fundamentally problematic nature of determining "efficacy" from complex clinical

trials—and the rhetorical basis of the disagreement between Genentech and the FDA—can be seen in two entries about Avastin in Genentech’s “BioOncology Timeline,” both listed under 2005:

Data from Phase III study of Avastin plus paclitaxel chemotherapy met its primary endpoint of improving progression-free survival in first-line non-squamous non-small cell lung cancer.

Data from Phase III study of Avastin plus paclitaxel chemotherapy met its primary endpoint of improving progression-free survival for first-line treatment of metastatic breast cancer. (Genentech, 2012)

Since so much controversy has grown up around the approval process for the breast cancer indication, yet no problems arose around the approval of the lung cancer indication, it seems clear that Genentech’s too-clean perfect mirror-image statements about the two indications is strategic, designed to indicate that there is no difference between the two indications in terms of their trial outcomes. Of course, the process is not as simple as these statements suggest, nor was the 5-4 decision the end of Avastin’s chances for a breast cancer indication approval. Despite the committee’s decision against Avastin, the FDA actually *ignored* the committee’s recommendation (a relatively rare although not unheard-of action) and granted the breast cancer indication under what is called “accelerated approval.”

The accelerated approval process has been under more or less scrutiny, and has been the subject of increasing and decreasing but never quieted debate, since its inception in 1992. Largely in response to the activist AIDS movement, which shamed the FDA about its slow approval processes for potentially life-saving drugs and demanded more patient access to experimental treatments, the accelerated approval process has several key elements. First, accelerated approval can only be used for “serious” conditions with “unmet medical needs” (United States Food and Drug Administration [FDA], 2012).

Defining either of these terms with any kind of accuracy or consistency continues to be difficult and contested, but neither is the source of the deep contention between the FDA and Genentech. The term most contested between them, and indirectly referenced in the Genentech timeline cited above, is “surrogate endpoint.” The accelerated approval process allows drugs for serious illnesses, for which an unmet need exists (few drug options, essentially), to bypass the higher standard of full FDA approval, which generally requires improvement in what is called “Overall Survival” (OS), a measurably longer overall life expectancy in the medication group over the control group. Instead, accelerated approval may be granted on the basis of other, less-certain endpoints, including the one at issue in the Avastin breast cancer hearing, “progression-free survival” (PFS). The FDA, in its “Guidance for Industry” on “clinical trial endpoints for the approval of cancer drugs and biologics” (2007) defines PFS as “the time from randomization until objective tumor progression” (p. 8). In other words, PFS is a measurement of how long patients go without tumor growth after their initiation into the study.

It is not within the scope of this project to tease apart the meanings and applications of the various clinical endpoints generally or the contested definitions and purposes of the PFS endpoint specifically (although both of these could be profitable areas of study). Rather, what is important here about the accelerated approval process and its “surrogate” endpoints is that both are relatively new and highly contested, with the FDA, Congressional oversight committees, pharmaceutical companies, and patient groups struggling to control their meanings and interpretations. As a result, drugs approved under the accelerated approval process often operate in a universe of higher

scrutiny and can offer insights into the contested boundaries of the FDA's power, as well as the terms of its debates with industry and patients. Moreover, because the accelerated approval process includes an "accelerated withdrawal" clause, something can occur in the world of accelerated-approval drugs that almost never occurs with drugs approved in the slower way: a drug's approval can be withdrawn. While it is true that, very rarely, FDA approval is withdrawn from drugs that received full approval, generally a very large-scale (and highly publicized) tragedy must occur for that to happen. For example, Vioxx, approved by the FDA in 1999, began to raise questions within the agency as early as that same year, and studies over the next decade led to stronger and stronger labeling requirements from the FDA. However, it was not until 2010 that Merck, the maker of Vioxx, "voluntarily" withdrew Vioxx from distribution. As late as 2005, an FDA committee allowed Vioxx to return to U.S. markets, as long as it had very stringent labeling. With Avastin's breast cancer indication, however, the turnaround between accelerated approval and withdrawal was (for the FDA) very fast: in 2010, just 2 years after the agency decided to override its own advisory board and grant accelerated approval, another committee voted 12-1 against full approval, and the breast cancer indication was essentially withdrawn⁶.

It was this withdrawal, after 2 years of wide distribution and continuing experimental trials, that led to the outbreak of indignation from Genentech and from cancer patient organizations. It was this withdrawal, and the regulations that govern it, that led to the hearing that is the central focus of this project. On June 28 and 29, 2011, the FDA held a "public" hearing about the breast cancer indication. The Oncologic

⁶ Official withdrawal by the agency took somewhat longer, in part because of the hearing that is the subject of this study.

Drugs Advisory Committee panel convened to oversee the hearing voted unanimously (6 to 0) to maintain the drug's withdrawal.

This hearing is an ideal case study for a first outline of a rhetoric of bureaucracy for several reasons. First, because this is one of the relatively unusual cases in which a bureaucracy or its representatives must actually sit in front of a public audience and justify its decisions, processes of decision making that are normally hidden, and rhetorical strategies that are normally implicit, come into the public view and are made explicit. Because the agency had to argue for the validity of its own processes, in other words, the rationalities behind and rhetorical justifications for those processes became visible.

Second, this is a particularly telling case for demonstrating the importance of interchangeable roles and role-based rhetorics (as opposed to “community” or “disciplinary” rhetorics) as keys to bureaucratic rhetoric because the representatives of the FDA in this case—the voting members of the advisory committee—are not in fact FDA employees, at least not exactly. They are outsiders, selected on the basis of their technical expertise, who may serve “a specific term” (at the discretion, largely, of the FDA commissioner) and may even be temporary members serving only for one meeting (United States Government Accountability Office, 2008, p. 1). The temporary and “outsider” nature of these voting members raises a very interesting question at the heart of the modern bureaucracy: how and why do the constantly-rotating, interchangeable members of a bureaucracy, even those who serve only for a single meeting, so completely adopt the rhetoric of the bureaucracy that it overcomes all other disciplinary, community, and personal rhetorics and commitments?

Finally, this FDA hearing is an ideal case study for a (beginning of a) rhetoric of bureaucracy because it so clearly demonstrates the underlying tensions and conflicts between bureaucracy and politics—and thus calls into question the notion that we as rhetorical scholars can subsume the study of bureaucratic rhetorics under the larger umbrella of political discourse. The hearing enacts the struggle between bureaucracy and politics in its very set-up, in which “the public” stands on one side of a barrier, speaking from their personal experience, calling upon the FDA to validate individual experience and equality of access, while “the bureaucracy” (including its corporate partner Genentech) make procedural decisions from the other side of the barrier. This is, in other words, the drama of politics versus bureaucracy writ small, all of its actors (the public, corporations, agency representatives, and “experts”) present, all of the dynamics of the fight compressed into 2 days of testimony.

By performing rhetorical analysis on the transcripts of this unusual and unusually representative hearing, then, this project will identify the key characteristics of bureaucratic rhetoric, demonstrate the importance of procedure and role in making that rhetoric powerful across constantly-shifting personnel turnover and varying situations, and offer insights into who it is that bureaucratic rhetorics address. The following chapter will discuss the method and theory by which the analysis has been performed, the next two will offer in-depth discussions of that analysis, and the final chapter will suggest not only the ways in which a rhetoric of bureaucracy might inform rhetorical theory generally and rhetoric of science specifically, but how understanding such rhetorics reveals the ways in which bureaucratic power grows and is wielded, and possible modes of resistance to that power.

CHAPTER 2

METHODOLOGY AND THEORY

This case study attempts to answer three questions: *how* does a bureaucratic agency justify its decision-making processes; *to whom* does it justify those processes (who is the agency's rhetoric designed to persuade); and *in what ways* does the bureaucracy achieve facticity for its own procedures and interpretations through this process of justification? Rhetorical analysis is an appropriate methodology for answering such questions for several reasons. First, it is amenable to a variety of methods, including for example, coding and intertextual comparison. Because this project attempts to address more than one question about the hearing transcripts being studied, a methodology that allows for several methods is useful and offers multiple ways into the texts. Second, and perhaps more importantly, this project attempts to bring a sociological concept—the structure of bureaucracy as outlined by Max Weber and his followers—under a rhetorical eye. What this means is that while Weber and others have already identified and characterized *what it is* that bureaucracy does, this project attempts to add to that understanding by showing how, rhetorically, that bureaucratic work is done.

Rhetorical analysis has already been shown to be effective at this kind of extra-disciplinary appropriation, especially in the rhetoric of science. Rhetorical analysts like Greg Myers (1990) brought the terminology and concepts of literary theory into rhetorical analysis, for example, and the scholars whose work is collected in Jack Selzer's

Understanding Scientific Prose (1993) imported not only literary theory generally, but feminist and Marxist reading strategies and even biological and architectural concepts into the study of how scientific texts persuade.

Methodology: Rhetorical Theory and “Importation”

In general, rhetorical analysts have felt free to adapt the theories and concepts of other disciplines to the rhetorical reading of texts. They have done so in two main ways, and for two good reasons—but also with one very important caution or caveat. The ways in which rhetoricians have brought other disciplines’ concepts and strategies into rhetorical reading are twofold. The first is by adopting the viewpoint of the discipline in question. For example, in Davida Charney’s (1993) “A Study in Rhetorical Reading: How Evolutionists Read ‘The Spandrels of San Marco,’” Charney notes that many outsiders have read the text, then asks, “But what of the real scientists who read ‘The Spandrels of San Marco?’” In other words, Charney wants to read the text like a scientist—to identify “how scientific readers cope with rhetorical strategies that generations of scientists have been trained to condemn as unscientific” (p. 206). This approach—the attempt to read a text in the way that it might be read by readers within the discipline for which it was written—corresponds to the first reason rhetorical analysts import the concepts and perspectives of other disciplines into our work. That is, one reason to do this kind of importation is to find out *in what ways* other disciplines are rhetorical: who, and how, do these disciplines intend to persuade and argue, and how do their internal audiences perceive the discipline’s texts?

The second way in which rhetorical analysts have imported the theories and concepts of other disciplines into the rhetorical readings of texts is by using those theories

and concepts to create new or revised *ways of reading* the texts. Rather than answering questions about how the originally intended disciplinary audience might have understood the text as rhetorical, these approaches answer questions about how other disciplines' knowledges might provide us with new ways of understanding textuality. Again, Selzer's collection is informative (it did, after all, attempt to bring together as many models for "understanding scientific prose" as possible).

Specifically, Barbara Couture's (1993) chapter, "Provocative Architecture: A Structural Analysis of Gould and Lewontin's 'The Spandrels of San Marco'" indicates the ways in which imported concepts from another discipline can offer new ways to see or understand the functions and workings of a text—new ways to read rhetorically. By drawing a strong analogy between "structural" readings of texts (based in Saussure, another theorist "imported" into rhetorical analysis) and the physical "structures" of architecture used as metaphors in the text she is analyzing, Couture argues that "[t]he architectural metaphor developed in 'Spandrels' suggests that meaning in this essay is revealed in its structures" (p. 276). Although varieties of structural analysis had certainly been conducted before this one, Couture's importation of architectural terms and concepts both literalizes the metaphor behind "structural" readings and also, and more importantly, offers her a very specific and appropriate method for reading *this particular text*, for specializing the vocabulary and method of rhetorical analysis to the context, purpose, and language of the text she is studying. This second way of importing other disciplines' concepts and theories into rhetorical analysis, then, corresponds to the second purpose for doing so: to identify new ways of reading, new *things to look for* in a text. Often, these are designed and applied for and to a specific text being studied and are

therefore very effective for particularizing the very broad approach of rhetorical analysis to a given object of study.

The caution or caveat to which all of these importations are subject is that all theoretical, methodological, and conceptual terms are loaded and heavy with baggage. For example, Couture uses some architectural terminology to literalize the “structuralist” metaphor, and in doing so, she strips the terminology of much of the embedded implicit meaning it carries for those in the field of architecture itself. The first kind of importation—the attempt to read texts as its intended disciplinary audiences would read it—does try to overcome this barrier as much as possible, but the carrying-over of terms and concepts from one discipline to another always entails the possibility, even the probability, of attenuation. This does not mean that such approaches are illegitimate or even overly problematic; it merely means that any study (such as this one) that attempts such importations must be aware of, and either mitigate or argue against mitigating, the shifts in meaning and the loss of theoretical depth that result. This study will argue that the application of sociological concepts of bureaucratic structure to rhetorical analysis can offer us new ways in which to read and understand the texts of and around bureaucracy; in other words, I will be doing the second kind of importation, the use of concepts from another discipline that allow a particularization of rhetorical theory to a specific text. In doing so, I will also address the issue of theoretical attenuation and argue that it does not negate the value of importing certain sociological concepts for the reading of bureaucratic texts.

Method: Particularization of a Two-Stage Rhetorical Analysis
to Bureaucratic Texts

Briefly put, I will be using “imported” sociological concepts to adapt Leah Ceccarelli’s (2001) two-stage approach to rhetorical analysis (from *Shaping Science with Rhetoric*) into a particularly appropriate set of methods for analyzing the legitimizing rhetorics of, and the audiences addressed by, a bureaucratic agency. Ceccarelli’s method is particularly appropriate for several reasons. In the first place, the objects of study in Ceccarelli’s book are closely analogous to the objects in this study, since Ceccarelli was looking at the ways that insiders in a particular group legitimized their work to and for a potentially resistant outsider group. She refers to the works she studies as “*interdisciplinary inspirational* works of science, because books of this kind attempt to stimulate the growth of community between different scientific disciplines.” Each of these works acts as a “catalyst,” creating reactions among (seemingly) unrelated disciplines (p. 4). Because these works attempt to “appeal to divided audiences” (p. 5), they must make explicit the assumptions and legitimating structures underlying their own claims in ways writers need not do when working within their own communities. In this way, the works Ceccarelli studies are similar to the FDA hearing, in which a closed group (the bureaucracy of the FDA) is addressing an outsider and potentially resistant audience (the public) and thus is forced to make its legitimating rhetorics explicit and visible.

Second, and more importantly, Ceccarelli’s two-part approach to rhetorical analysis specifically sets out to answer the two types of questions I am attempting to answer here: questions about a group’s legitimizing structures—what Ceccarelli calls “how readers might have been invited to respond to the text’s appeal” by the authors—

and about its audiences. For her, audience analysis is largely a “test” for the “hypotheses” constructed during the close reading; if the text “invites” its readers to respond to it in a particular way, Ceccarelli asks, then how can we know whether they have in fact done so? Her answer is to perform “intertextual analysis,” the seeking out of audience *responses* to the original texts that indicate whether the audiences have indeed responded as the text “invited” them to.

This part of Ceccarelli’s work is particularly relevant to my project because in addition to two highly effective texts—Theodosius Dobzhansky’s *Genetics and the Origin of Species*, which essentially created (or at least codified) the “modern synthesis” in biology, and Erwin Shrodinger’s *What is Life?*, which created a synthesis between the fields of physics and biology—Ceccarelli also analyzes a famously unsuccessful text, Edward O. Wilson’s *Consilience: The Unity of Knowledge*. At both stages of the process (during both the close reading and the intertextual analysis stages), Ceccarelli finds Wilson’s work to be singularly unconvincing, especially compared to the works of Dobzhansky and Shrodinger. Moreover, she finds that where the others generated consensus and synthesis, Wilson’s book generated, and continues to generate, debate and anger. By presenting the very audiences he was trying to persuade (social scientists and humanists, in particular) as less-informed and incorrect, depicting his own group of physical scientists as the “heroes” of the work, and using a language of “conquest” and imperialism rather than cooperation (p. 131), Wilson managed to convert an idea that was already acceptable and interesting to many of his readers into a battleground.

This is precisely the position of the FDA: despite large-scale agreement over the importance of public health and the regulation of pharmaceuticals for safety and efficacy,

and despite increased calls for transparency in all government agencies, increases in FDA transparency—an increase in the number of texts in which the bureaucracy directly addresses the public—have in fact correlated with *decreases* in public trust of these agencies. As the Pew Research Center found, the public's trust in the FDA fell from a very high 75% in 1997/98 to a modest majority of 58% in 2010 (Pew, 2010, p.1). These years were precisely those during which transparency around government agencies' workings—that is, public exposure to the agencies' internal rhetorics, decision-making processes, and legitimizing justifications—were at their height and were constantly increasing. Although the Freedom of Information Act (FOIA) was originally passed in 1966, it was only in 1996 that the Act was amended to specifically include electronic records, in the Electronic Freedom of Information Act (George Washington University [GWU], 2008, n.p.). As a result, millions of new documents suddenly became available not only to those who could physically access the agencies' records, but to anyone with an internet connection. Bureaucracies found their internal documents suddenly under the scrutiny of many publics—patients, doctors, and other stake-holders in the agencies' decisions—and at the same time saw an increased demand from successive presidents (especially Clinton and Obama) for increased interaction with the public in the form of hearings, direct communications, and websites for public access.

The current FDA, then, is in much the same position as Edward Wilson: it is promoting a concept (in the FDA's case, predistribution testing of drugs for safety and efficacy) that is widely lauded and approved, yet finding that the more explicit and visible its justifications of its own work, the less its audience trusts its mission. Thus, as Ceccarelli said of Wilson, the reasons for the FDA's failure to persuade are not merely

historical or political (the public is not simply “against” the FDA’s mission, nor is that mission considered inappropriate for the time and place), nor is it simply a matter of one side or the other being “wrong.” “It is neither a simple ‘truth,’” Ceccarelli writes,

that Wilson was wrong nor mere ‘politics’ that kept his theories from being accepted. In a way, we can say that it was both: Wilson was wrong to take the particular approach to unification that he did not because interdisciplinarity is a flawed idea but because his particular approach to unification was designed in a way that angered scholars who otherwise would have been open to his call to action. (p. 127)

Similarly, my project asks in what way the FDA’s “particular approach” to legitimizing and justifying their decision-making process was the wrong one to take, as well as (and the two questions cannot be separated) how that approach “was designed in a way that angered” the publics to whom it was supposed to be persuasive and who, indeed, might otherwise have been open to the FDA’s mission.

Thus, because of the close similarities between my project’s aims and hers, as well as the close analogy between her objects of study and mine, Ceccarelli’s two-part rhetorical analysis method is an appropriate one to adapt for this study. The question, then, is how I will “import” concepts from sociology to adapt Ceccarelli’s method to the study of the particular texts I am reading, the transcripts of the FDA hearing. Although rhetorical analysis is a primarily “inductive” method, based on close readings and rereadings of texts and the generation (rather than “testing”) of hypotheses, nonetheless, a rhetorical analysis can be driven by a particular theory or set of concepts in order to draw out of the text certain elements of its structure and function. For example, in her *Scientific Characters: Rhetoric, Politics, and Trust in Breast Cancer Research*, Lisa Keränen (2010) lays out a “three-part framework” (p. 21) that drives her rhetorical analysis. She draws on (and draws) distinctions between three classical or traditional

concepts in rhetorical theory—ethos, persona, and voice—and works through a large number of texts surrounding the “Datagate” breast cancer scandal by reading for and identifying the locations, intersections, and conflicts among these three types of “characterization.” Thus, although her early readings of her study texts were almost certainly inductive (these were the open-ended readings that brought her to the insight that “characterization” was important in the texts), her systematic analysis was driven by a search for particular terms, usages, and discourse patterns that reflected an ethos, persona, or voice approach to characterization.

Many rhetorical analysts, despite a commitment to the inductive nature of textual research, similarly manage and direct their analyses by the application of theories or concepts, through which they read the texts for instances of particular textual patterns. In addition to allowing a researcher to manage a massive corpus like the one Keränen studied, this approach also allows rhetorical analysts to approach the same text from many angles, identifying different processes at work and providing a layering of (demonstrated, validated, supported) claims or theories about the text that collectively make sense of its multiplicities. As detailed below, I will be “importing” Max Weber’s (and his followers’) sociological conception of bureaucracy into the first part of this project in order to understand what I will call the *legitimizing rhetoric* of bureaucracy—in other words, the specific cluster of ways in which a bureaucracy enacts and justifies its rationality, or its approach to decision making. In the second part of the project, I will “import” Latour’s concept of FLS or facticity to inform an analysis of which audiences are being addressed (or not) by the FDA’s bureaucratic legitimizing rhetoric and to

suggest an explanation for why the FDA in fact need not persuade its *apparent* audience, the public, but rather an internal audience synonymous and equivalent with “the record.”

Analysis of Legitimizing Rhetorics: Sociology and the Four Rationalities

Although in the first chapter I identified five characteristics of bureaucracy as suggested by the work of Max Weber (rule-based action, organization around roles in which individuals are interchangeable, reliance on “the record,” reliance on expert opinion, and an homogenization of individuals), I will focus on one of these—rule-based action—as an entrée into a more complete description of the self-legitimizing rhetorics of bureaucracy. That single characteristic is not only the one that most closely accords with rhetorical theory (more on this momentarily), but is also the one Weber himself returned to again and again as descriptive of bureaucratic life. For example, in noting that bureaucracy is characterized by disregard for “persons” as well as by rules, Weber (1978) claims that “the second element mentioned, calculable rules, is the most important one for modern bureaucracy. The peculiarity of modern culture, and specifically of its technical and economic basis, demands this very ‘calculability’ of results” (p. 200). In other words, for Weber *the* defining characteristic of modern bureaucracy, if there is just one, is the creation and impersonal enactment of calculable rules—that is, rules reducible to something as close as possible to an equation.

Weber also claimed that the basis of these rules must be *rational*, although there is some ambiguity in his use of that term. Whether it is the calculability, the systematicity, and/or the “formality” of the rules that makes them rational, or whether it is simply their creation by those the culture *considers* rational (the scientists, lawyers, and

other experts), is left unclear. However, more recent sociologists, especially Stephen Kalberg (1980), have worked through the various and ambiguous multiple meanings of rationality in Weber's work, and it is Kalberg's classification of what he calls Weber's "four types of rationality" that I will apply in conducting my rhetorical analysis. Before describing these types and their relevance to the FDA hearing, however, it is important to briefly consider both the relationship between rhetoric and rationality and the importance of the concept of rationality to a legitimizing rhetoric.

That rationality is a construct—and a fundamentally *rhetorical* construct—has been argued since at least the publication of Perelman and Olbrechts-Tyteca's (1969) *The New Rhetoric*. Like many other rhetorical theorists, they argue against the Enlightenment ideal of reason as separate from (and above) human construction, subjectivity, and culture. Specifically, Perelman and Olbrechts-Tyteca claim that the notion of a pure logical rationality, based on the perfect application of rules untainted by human subjectivity, an idea which had taken hold after the Enlightenment and gained power primarily through the sciences but also in law, was too limited to cover the realities of human argumentation. In their introduction, for example, they write that "It is the *idea of self-evidence* as a characteristic of reason, which we must assail" (p. 3, emphasis in original). They go on to tie rationality very firmly to language, noting that "the object of the theory of argumentation is the study of the discursive techniques allowing us to *induce or increase the mind's adherence to the theses presented for its assent*" (p. 4, emphasis in original). In other words, for Perelman and Olbrechts-Tyteca, rationality—that is, the ability to decide and to induce adherence to one's decisions—is fundamentally rhetorical.

This argument was taken up by the early rhetoricians of science in their attempt to justify their new field. Many outside the field of rhetoric, and quite a few within it, argued that science, because of its basis in a pure Enlightenment-type rationality insulated against human interference, was not amenable to rhetorical study. Richard Rorty (1987), among others, disagreed. In the first place, he suggested that “we can start by distinguishing two senses of the term ‘rationality’”—the first meaning simply “to be methodical” and the second meaning “knowing in advance what criteria” will be applied and then judging the outcome of a test, decision, or experiment by those criteria (p. 39). He then offers a third choice, an understanding of rational as meaning “something like ‘sane’ or ‘reasonable’ rather than ‘methodical’” (p. 40). Although he specifically argues for this third type, and for *its* fundamental rhetoricity, he also constantly undermines the purity and extra-humanness of the other two types, even the methodical and criteria-based rationalities of science and law. For example, he quotes Thomas Kuhn, who said that “‘there is no theory-independent way to reconstruct phrases like ‘really there’” (p. 41)—a claim that the natural phenomena under study are, in fact, “really there” being central to the justification of scientific rationality as pure and objective—and argues that the real basis of science is not so much an extra-human pure rationality but “intersubjective agreement,” which by definition relies on rhetoric for its achievement (p. 42). In other words, even in its most supposedly objective, pure, and formal instances, rationality is *always* rhetorical because even decisions about which criteria to base one’s decisions on or which methods to apply is always the result of “intersubjective agreement” achieved through language⁷.

Thus, the application of a classification of types of rationality to a rhetorical analysis is peculiarly appropriate: not only is a classification that identifies multiple rationalities already clearly more in line with a rhetorical understanding of rationality than an Enlightenment or “pure” concept of it, but a classification system describing types of rationality cries out for a rhetorical reading in the same way that the historians’ descriptions of Schrodinger’s and Dobzhansky’s books as “effective” cried out for one. As Ceccarelli puts it, “Taken together, these [historians’ and scientists’ descriptive] explanations of what Dobzhansky contributed to the evolutionary synthesis are satisfying, but only to a degree” because they “provide broad accounts of *why* this books succeeded in building a bridge between the warring camps. But these explanations only make preliminary and unsatisfactory claims about *how* this book was able to affect the influence it had” (p. 30). In the same way, Kalberg’s descriptive classification of the four types of rationality provides an excellent account of *why* there is conflict between different groups but no real account of *how* the different rationalities are enacted in specific situations and texts or *how* the rhetorical enactments of these rationalities, especially in direct interaction with one another, leads to the *domination* of one by another.

Before moving to a detailed description of the four types of rationality and the way I will apply them in this study, however, I would like to briefly note the importance of the concept of rationality to a study of legitimation or legitimizing rhetorics. If we accept the Rortian definition of rationality—or rather, *a* rationality—as a more-or-less

⁷ Of course, such decisions are also based on, for example, shared knowledge bases and shared understandings of phenomena. This caveat, however, simply strengthens the case; a shared knowledge base, for example, relies by definition on rhetoric (shared terminologies and definitions, shared texts and interpretations of texts, etc.).

systematic or methodical application of a set of rules, constructed through “intersubjective agreement,” to all or a set of problems, then *any* legitimizing rhetoric must be based on some particular rationality or another. As we will see below, these rationalities need not be recognizable in terms of the formal Enlightenment model; they may be sets of rules or criteria based on subjective, individual, or community values. Perelman and Olbrechts-Tyteca (1969) made a similar point in claiming that values are “objects of agreement that make possible a communion with regard to particular ways of acting” (p. 74), or in other words, that values *are* intersubjectively-agreed-upon criteria by which to make decisions, or in Rorty’s terms, they are “rationalities.” Even Stephen Toulmin (1958), whose argumentation theory is closely aligned with Enlightenment concepts of rationality in its attempt to break down all arguments into diagrammable series, nonetheless places at the very bottom of argumentation, as the foundation upon which all claims rest, the “warrant.” The warrant is an assumption about the world, or in other words, a (more-or-less) agreed-upon value or set of values. In addition, of course, “values” were one of the bases on which Aristotle claimed an argument could be constructed.

In short, any rationality simultaneously is based on and supports a system of intersubjectively-agreed-upon values, by which decisions can be made about which criteria to apply to situations and which methods to use. Any attempt to legitimize—that is, to explain the value of—a particular decision-making process, is thus by necessity based on, and simultaneously a justification of, a particular rationality. As we will see, it is in fact the legitimation and justification of their particular rationality, their intersubjectively-agreed-upon set of rules, criteria, and methods for decision making, that

the FDA works to achieve, as opposed to their much more limited *stated* goal (a goal in line with an Enlightenment concept of rationality and correct decision making as immutable and objective) of simply arriving at a determination about the safety and efficacy of a particular drug. Put another way, the hearing is at least as much an attempt to legitimize the rationality by which their decisions are made and reinstate that rationality as unassailable as it is an attempt to make a decision about a drug. Thus, an identification of the conflicting rationalities—and the ways in which competing groups attempt to justify those rationalities, what I am calling their “legitimizing rhetorics”—is really a justification of a particular set of values. The first part of my analysis will attempt to identify the conflicting rationalities and their legitimizing rhetorics in order to understand not only why but *how* the FDA maintains the primacy of a bureaucratic approach to public health, as well as how their particular way of legitimizing their rationality is causing conflict with the publics who otherwise support its mission of ensuring the safety and efficacy of pharmaceuticals.

Given, then, that rationality is a rhetorical construct and that a rhetorical reading of competing rationalities can add a “how” dimension to the “why” answers provided by sociological classifications, and furthermore that identifying and characterizing a group’s rationality is fundamental to understanding how it legitimizes itself (especially when confronted with potential opponents), let us turn to Kalberg’s (1980) classification system and identify the ways in which it will be used in this project to drive a rhetorical analysis of legitimizing rhetorics. Kalberg noted that the two dominant Weber scholars tended to misuse or overlook the ambiguities around the term “rationality” in Weber’s work,

especially *Economy and Society*, in which Weber described the workings of bureaucracy in the most detail. Their misuses of Weber's terms, Kalberg writes,

are plagued by a common shortcoming: both note 'usages' or 'dimensions' of rationality that cannot be consistently traced back to the frequent discussions of 'rationality' and rationalization processes in *Economy and Society* (*E & S*) and the *Collected Essays in the Sociology of Religion* (*CESR*). Moreover, their definitions do not coincide with Weber's various historical-sociological analyses of the paths followed by rationalization processes in different civilizations. (p. 1146)

In other words, Kalberg's argument is that the two major sociologists who had used Weber's concepts of rationality in their own work had both underestimated the complexity of Weber's uses of "rationality" and had also attributed to Weber definitions of rationality that were not traceable to his original work.

Kalberg set out to correct this problem by scouring Weber's work for all his uses of the term, then classifying them into four types: "practical, theoretical, substantive, and formal" (p. 1151). Each of these, he argues, is rational in the sense that it drives "regularities of action" (p. 1148) based on an assumed or common purpose or goal. In a section that shows the tight correlation between Weber's sociological understanding of rationality as multiple, contextual, and relevant only in a given "sphere of life" (p. 1150) and the more recent understanding of rationality as rhetorical, Kalberg writes that "Weber argued that man did not acquire his 'rationality' with the Enlightenment and that individuals in all previous epochs were not incapable of rational action" (p. 1148). Rather, their rationalities (which still persist) were based on different patterns of action toward different goals. Each type, in other words, was a set of "*conscious* regularities of action that [...] serve[d] to master (*beherrschen*) fragmented and disconnected realities" (p. 1148). The four types of rationality, then, are four ways of regularizing reactions to

uncertainty and achieving purposeful action (the two main goals of the FDA as well, as we will see), and each of the four legitimizes different responses to, and processes for dealing with, uncertain situations.

The first type, “practical” rationality, “views and judges worldly activity in relation to the individual’s purely pragmatic and egoistic interests” (p. 1151). Practical rationality, Kalberg writes, “accepts given realities and calculates the most expedient means of dealing with the difficulties they present” (p. 1152). The archetypical proponents of practical rationality are “merchants, artisans, traders,” the corporatists, capitalists, and commercial operators (p. 1152). Those who legitimize their actions on the basis of a practical rationality, Kalberg notes, tend also to distrust “not only all striving after the impractical values of ‘the beyond,’ whether religious or secular utopian, but also the abstract theoretical rationality of all intellectual strata” (p. 1152). The strongest synopsis of this type of rationality and its means of legitimation—as well as its relationship to capitalist and corporate philosophy—is Kalberg’s statement that practical rationality “implies a subordination of individuals to given realities” (p. 1152)⁸.

The second type of rationality, “theoretical rationality,” is defined by Kalberg as “a conscious mastery of reality through the construction of increasingly precise abstract

⁸ In relating these rationalities to the FDA hearing (as I will do in the next chapter), it is tempting to assume a neat breakdown in which the corporatists in the form of the pharmaceutical giant Genentech-Roche not only are the sole embodiments of the practical rationality but also that they embody that rationality to the exclusion of all others. As we will see, the one drawback to Kalberg’s classification system, and a typical problem with classification systems generally, is a tendency to draw too simply and discretely the lines between “types.” The analysis section of this project will blur those lines somewhat and also suggest that it is almost exclusively the FDA speakers who adopt a “pure” version of one rationality and that this is precisely the agency’s problem in arguing its legitimacy.

concepts rather than through action” (p. 1152); in the realm of academics and theoretical scientists, this rationality involves abstract logic and “a cognitive confrontation with one’s experience” (p. 1152). Rather than arguing that such a rationality began with the Enlightenment, however, as some scholars have done, Weber “discovered a great variety of systematic thinkers who practiced this type of rationality” throughout history, even back to and before the Classical period. “In the earliest stages of history,” Kalberg writes, “sorcerers and ritual priests sought abstract means of taming nature and the supernatural” and thus used a form of theoretical rationality to legitimize their actions and their power over others (p. 1153). Those whose work is legitimized on the basis of theoretical rationality, Kalberg goes on to say, seek a “comprehensive ‘holistic’ explanation” of the world and are driven “to transcend sheer given routine and to supply the random events of life with a coherent ‘meaning’” (p. 1153). Here we begin to see both the potential for deep and fundamental conflicts between groups legitimizing their actions on the basis of different rationalities, as well as the potential for Kalberg’s classification to help us make sense of the reasons for the *non*-persuasiveness of the FDA to those who do not accept its rationality as the basis for public health decision making. Clearly, a group whose actions are legitimized on the basis of pragmatic advancement of individual interests and who distrust “the beyond” will have difficulty even coming to agreement on the terms of debate with those whose basis for correct decision making is purely or primarily theoretical, and which may be uninterested in or uncommitted to action in any form, at least without a comprehensive systematic understanding of the problem in place first.

To add to the complexity inherent in any attempt to bring diverse groups into consensus, the third type of rationality adds a new dimension: values. “Like practical rationality but unlike theoretical rationality,” Kalberg writes, “substantive rationality *directly* orders action into patterns.” However, while practical rationality bases its actions upon individual interests, substantive rationality solves problems and legitimizes actions “in relation to a past, present, or potential ‘value postulate’” (p. 1155). By this, Kalberg means that no single value, but rather a coherent system of values, drives substantive rationality. Above, I argued that *all* systems of rationality are based on value systems, but Kalberg here uses a narrower definition of “values.” While I argued (and Kalberg’s classification supports the notion) that each rationality is based on its own understanding of *what is valuable*—for example, a theoretical rationality may be based, albeit implicitly, on the idea that scientific knowledge is in itself valuable—substantive rationality more specifically legitimizes its actions on the basis of a value system of right and wrong, a more traditional and narrowly-defined understanding of “values.” In particular, Kalberg notes, the “value postulate” on which a substantive rationality is based is not necessarily, and in fact by definition may *not* be, justifiable or provable through scientific or empirical evidence. Moreover, Kalberg’s discussion of substantive rationalities deepens the problem of attempting to work through decision-making processes with participants using different rationalities. Each of the rationalities may well see the others as “irrational,” as “to the modern intellectual who trusts only science and empirical knowledge, the religious man’s reliance on faith remains within the realm of the ‘irrational’” (p. 1156). When conflicting rationalities interact, in other words, they

perceive one another as “irrational” rather than differently rational, and no common basis exists upon which a consensus for action can be achieved.

Finally, the most obvious culprit in the designation of other forms of rationality as “irrational” is the type both Kalberg and Weber ascribe to bureaucracy: “formal rationality.” According to Kalberg, “formal rationality ultimately legitimates a [...] means-end rational calculation by reference back to universally applied rules, laws, or regulations” (p. 1158). In other words, “universalism and calculation in reference to enacted regulations stand here strictly opposed to decision making in reference to the personal qualities of individuals concerned” (p. 1158). Formal rationality’s purpose is not to come to *certain decisions*, then, so much as to ensure that *certain processes* are followed—and that the people involved in making decisions continue to adhere to those processes. Interestingly, Kalberg divides science into two types with competing rationalities, noting that “[a]s opposed to the formulation of hypotheses, which belongs to the domain of theoretical rationality, experimental scientific procedures are [...] judged, by Weber, to be fully formally rational” (p. 1159). Dividing science in this way opens many possible debates, all of which play out in the FDA hearing: debates about the true role and legitimacy of science, about the relationship between scientific legitimization rhetorics and bureaucratic ones, and about which type of rationality reflects “true” scientific values. All of these questions will be important in the following analysis chapters. However, for now, the importance of formal rationality is its relevance to the case study undertaken in this project: formal rationality is *the* rationality employed by bureaucratic speakers in the FDA hearing; it opposes and labels “irrational” all the other types, including those employed by the (apparent or supposed) audiences of the

bureaucracy; and it is the primary reason for the inability of the FDA to effectively persuade the public of the value and legitimacy of its decisions.

In short, this first “importation” of concepts from another discipline, the importation of Kalberg’s classification of rationalities (based on Weber), will drive my analysis of the legitimizing rhetorics of the various speaker groups involved in the FDA hearing. In particular, I will focus on the conflicts between the FDA’s representatives and the public, arguing that the FDA speakers employ a purely formal rationality to legitimize their actions, a rationality fundamentally at odds with the public’s rationality, which I will argue is “practical-substantive,” a combination of two of Kalberg’s types. Before moving to that analysis, I will address the second “importation” from another discipline, the use of the linguistic concept of “reformulation.” If identifying the incommensurate rationalities of the speaker groups at the hearing help us understand how and why the FDA is not persuasive to its public audience, tracing the ways in which statements are “reformulated” over the course of the hearing helps us understand why the FDA *does not need* and *does not intend* to persuade that public, that in fact its true audiences are elsewhere.

Audience Analysis: Intertextuality in Two Forms

While the analysis of rationalities is intended to (begin to) answer the question, *how does a bureaucracy persuade*, the second type of analysis undertaken in this project will attempt to answer a different question, *whom* does the bureaucracy intend to persuade? This audience analysis will take two forms. The first will be brief and will simply demonstrate that the apparent audience—the members of the public standing directly in front of the committee and actually affected by its decisions—is neither

persuaded, nor is persuasion of this audience the purpose of the hearing. In other words, unlike politics, bureaucracy does not intend, nor does it need, to persuade the public, or any outside audience. The second half of the audience analysis will attempt to determine who—if it is not the public—the true audience of the bureaucracy in fact is.

In order to answer these slightly different questions, I will use two approaches. In keeping with my use and adaptation of Ceccarelli's two-part (textual and intertextual) rhetorical analysis method to identify both the legitimizing rhetorics and the audiences of bureaucracy, I will perform two types of "intertextual" analysis in this second section, one of which draws on a more typical conception of intertextuality and the other of which proposes the hearing itself as an intertextual situation (rather than seeing the entire hearing transcript as a single text, as the first part of the analysis will do). For Ceccarelli (2001), the purpose of the intertextual stage of a rhetorical analysis is to identify whether the rhetorical strategies—the attempts at persuasion—employed by the texts, the ways in which "readers might have been invited to respond to the text's appeal," in her words (p. 8), have actually been effective in persuading their intended audiences. I will again adapt her method, using it for slightly different interpretive ends. In short, where she asks whether the texts have been persuasive to a *particular* audience (which is appropriate for her work, as she is asking questions about whether certain texts are persuasive to particular readers in specified disciplines), I will instead be assuming that the texts need not be persuasive, *per se*, to any individual or group, but instead must be intended to produce some predetermined outcome. Rather than asking whether a text has been effectively persuasive, I will ask to what audience it speaks and what it attempts to accomplish—and whether it has done so. Thus, my approach is very similar to

Ceccarelli's but takes a slightly broader view of what texts attempt to do, with persuasion as just one possible effect to be achieved, out of a larger group of potentially desired effects.

In this first, briefer section of the audience analysis, I will locate and analyze a number of texts outside the hearing transcript that refer to it; this is the sense of "intertextuality" that Ceccarelli herself employs when she studies, for example, reviews of the books whose persuasiveness she is testing. Ceccarelli derives her concept of intertextuality not from the tradition in Discourse Analysis (which is perhaps more commonly cited) but from her own background, and the background of her methodological influences (especially Greg Myers) in literary study. Specifically, she discusses intertextuality in terms of "reader-response criticism and reception studies" (p. 8) because of her focus not on shared discursive elements but on the responses of later texts to earlier ones. In this way, both are focused more on the rhetorical and persuasive aspects of intertextuality (how readers' responses to a text can indicate whether it was successful and in what ways) than in the particular discursive features shared among texts (which a concept of intertextuality derived more directly from DA would focus on).

I draw on Ceccarelli and her rhetorical and reader response-inflected concept of intertextuality because the intertextual analysis in my project will specifically address patient and clinician responses to the Avastin hearing and its procedures (both before and after it actually occurred). Through analysis of the texts in which affected groups discuss the hearing, I will identify whether or not patients and clinicians are persuaded that the FDA made the right decision about Avastin; this answers the first important intertextual or audience question: is the *apparent* audience of the FDA hearing (the members of the

public, patients, family members, and clinicians sitting in front of the FDA committee—those speaking and being spoken to) actually persuaded by the committee? This question addresses audience in a very traditional sense, the sense Aristotle intended and which has driven much audience analysis since: the sense of audience as *those directly addressed*. Clearly, in a hearing, the directly addressed audience is the group sitting in front of the speakers, listening and (to a limited extent) responding.

Analysis of Potential Audiences: Linguistics and Rhetorical

Reformulations

The second and more in-depth section of audience analysis will seek to understand audience more broadly, as *those who must be addressed*, whether they are in the room or not, are visible or invisible in the hearing, are represented in a single person, a group, or an institution, and are singular or dispersed. Certainly mine will not be the first study to understand audience in this way; however, my study will attempt to keep the concept of audience as open as possible in order to understand who or what the FDA committee does, in fact, believe it is addressing. In short, the first part of the analysis—the traditional intertextual analysis—having demonstrated that the apparent audience, the patients and clinicians, is not the persuaded audience, this second part will import the linguistic concept of “reformulations” to determine who or what bureaucratic speakers believe their true audience to be.

This second section will also employ the concept of intertextuality more fluidly than Ceccarelli’s work does. While she made use of a strict concept of textuality to determine her intertexts—other written works related to the ones she was studying—my study is based on a slightly more complicated form of text: a transcript. A transcript is a

hybrid form of text in the sense that it is simultaneously a record of spoken language and a complete written text in itself. In the first part of this study (the analysis of legitimizing rhetorics), the transcript is conceived of as a singular entity, a written text like a book or article. In this form, the transcript is self-contained, and the rationalities of the various speaker groups can be analyzed simply as they appear in the transcript—as they are used, in other words, in the bounded moment of the text. Although informed to some extent by historical background, the legitimacy rhetorics analysis takes advantage of the material advantages of texts as Greg Myers (1990) described them, especially the advantage he described in saying that “texts hold still” (p. 6). The legitimizing rhetorics of any group or institution are constantly, albeit subtly, changing with changes in policy, history, interaction with other groups and institutions, and so on. A study of a single text like a hearing, then, is an effective means of getting an idea of the ways in which an institution or group legitimizes its practices without having to constantly account for thousands of (generally slight) contextual differences from one institutional moment or situation to the next. As Myers puts it, “written texts can function as evidence on this basic level” for “the practical reason that [readers] can do things with them that [they] cannot do with other data” (p. 7). Read as such a discrete and unitary text, the hearing functions as a static and therefore useful but somewhat manufactured object from which to “read” legitimacy rhetorics.

However, the transcript can also be read diachronically, as an event happening in time—that is, as a replaying of the events of the hearing, the spoken dialogue. Reading the transcript in this second way allows the various speakers’ statements within the hearing itself to act as a second form of intertext. In addition to analyzing the *written*

responses of the patients and clinicians to the hearing, the audience analysis section will also, indeed primarily, analyze the immediate *spoken* response of the hearing participants to one another, reading these responses as intertextual and therefore indicative of the effectiveness or ineffectiveness of the persuasive strategies of the speakers just as book reviews functioned in this way for Ceccarelli's study. In this reading of the transcript as a collection of intertextual responses—as a set of discrete spoken texts that respond to and (attempt to) revise one another—I will employ the linguistic concept of reformulation. Specifically, I will ask in what ways speakers attempt to revise or correct one another's texts within the context of the hearing and how these revisions or corrections can indicate first, whether and which audiences *are* addressed, and second, who or what do the bureaucratic speakers feel the *need* to address.

My hypothesis in this section, based on Weber's sociological analysis of bureaucracy and on an already-completed pilot study, is that the addressed audience of any bureaucratic speaker or group of speakers is not a traditional audience at all, in the sense that it is not a person or group of people or institution. Rather, the addressed audience of bureaucratic texts is *the record*. I will discuss this hypothesis more below. First, however, the concept of reformulation and its value in analyzing audience will be explained in more detail.

Audience Analysis Stage Two: The Reformulation of Claims

In linguistics, the term “reformulation” refers to an apparently simple action, “mak[ing] the same point in different words” (Levinson, 1983, p. 331). Such reformulations can be employed in one of two ways—by restating another's phrasings in new words or by restating one's own previous statements. A reformulation is thus a near-

repetition that, despite an apparent function as repetition, may in fact change the meanings of phrases, and their significance in a particular context, very materially. Frank Luntz (2007), for example, describes (proudly) a famous and often-cited reformulation for which he was largely responsible: the change from the use of the term “estate tax” to the term “death tax.” While the technical definition—that is, the number and wealth of people actually affected by the tax—is not changed by the term, citizens’ perception of the two phrasings is widely different, suggesting that simply saying “the same thing” in other words is a potentially powerful strategy for changing beliefs. Moreover, linguistic scholarship on the functions of reformulations in discourse, until recently nearly exclusively “descriptive,” has taken a critical turn and begun to acknowledge the ways in which reformulations, even those employed in less politically-critical settings and even in one-on-one dialogue, can enact power differentials and create hierarchies among people.

In particular, the didactic effects and purposes of reformulation have been of interest, albeit so far almost exclusively to those studying second-language instruction in English. The spoken attempts of second-language learners, these studies suggest, is “corrected” or “repaired” by native speakers during the learning process (see for example Nassaji, 2007; Yang & Zhang, 2010). In a similar vein, Guiomar Ciapuscio (2003) argues that reformulation also plays a didactic role in interactions between experts and “(semi-) laypersons” (p. 207). It is this revision or “repair” role, by which speakers use reformulations of their own or others’ statements to “correct” what has been said, that is of interest in the FDA hearing. Specifically, the FDA speaker groups use reformulations to “correct,” not errant but alternate or competing interpretations, indicating that the purpose of their speech is not to persuade those present but to achieve Latour’s Fact-Like

Status or facticity for their own bureaucratic approaches to public health and their own attenuated concept of medicine.

The identification of reformulations in the text indicates the ways in which the transcript meets Ceccarelli's definition of "intertextual" analysis, despite differing significantly from her initial concept of intertextuality. In short, reformulation analysis allows the analyst to read the hearing not as a single text, but as a collection of intertextually-related discrete statements. As a record of a series of spoken texts that are interrelated and that attempt to revise and correct one another, the hearing can thus be read as encompassing both speaker(s) and audience(s) within itself. Moreover, the line between speaker and audience is blurred because speakers are also audiences of other speakers, and vice versa. This complexity requires an adaptation, and an expansion, of Ceccarelli's intertextual audience analysis, which was based solely on the traditional concept of text as written and audience as secondary—as reading the completed argument and responding after the fact. In the FDA hearing, the audiences are also the speakers, and responses can occur during the course of the creation of the "text" (the transcript) itself. Thus the concept of reformulations is useful because it not only constructs speakers as both audiences and speakers simultaneously (each speaker, after all, not only speaks to his or her own purpose but does so by responding to and changing other speakers' statements, a move that requires them to be audiences), but because it provides a terminology by which to understand the ways in which a speaker can *appear* to simply restate what has been said but actually revises and "corrects" it to match his own, rather than the original speaker's, intentions and purposes.

In fact, it can be argued that almost *every* instance of intertextuality is to a greater or lesser extent an instance of reformulation. Aside from direct quotes (which are only debatably exact repetitions, since as Ruth Wodak (2008) argues, “By taking an argument and restating it in a new context,” we see that the argument “then acquires a new meaning because meanings are formed in use” (p. 3)), any reference to or use of someone else’s words—or even one’s own prior words—requires some form of revision. As Norman Fairclough (1989) puts it in reference to authors’ uses of and references to their intellectual opponents, “The point is that in alluding to opposition texts in the intertextual context, producers standardly reformulate them, substituting for the wording of their opponents an ideologically contrastive wording of their own” (p. 188). The same applies when one reformulates one’s own words, especially in the attempt to make one’s statements more acceptable or persuasive to one’s intended audience.

Reformulations as Indicators of Audience

The remaining question about reformulations is what they can tell us about both the effectiveness of particular statements in persuading the apparent audience of the hearing and about who or what the addressed audience of the bureaucratic speakers might be. It would certainly be overstating the value of such an analysis to claim either that it can *prove* that the direct audience is, during the hearing or at some later time, persuaded (or not), or that it can single out and unquestionable identify the audience to whom the bureaucracy speaks. Like any rhetorical analysis, this one does not seek to prove; rather, the power of any rhetorical-analytic approach lies in its ability to account for particular effects at the textual level. In this sense, an analysis of reformulations is very powerful in

providing insight into, if not proofs about, the particular audiences being addressed by the bureaucracy in the Avastin hearing.

In the first place, reformulations can at least suggest the ineffectuality of the speakers at persuading one another. Reformulations show, for example, that no speaker group in the hearing ever agrees to statements made by any other speaker group without serious amendment based on different aims and purposes. This is the key to using reformulations to identify a group or speaker's effectiveness, or lack of it, in addressing a particular audience. If during the dialogue every statement even of supposed agreement is phrased in such a way as to actually amend, revise, or correct the original with which it apparently agrees, then the reformulator has not been persuaded, but is only phrasing opposition in terms that appear conciliatory. Speakers are actually speaking to promote their own agendas, even when seeming to concede.

What this suggests, and what I will argue in the audience analysis chapter, is that in fact, none of the bureaucratic speakers *intend* to address the public audience present at the hearing or bring any of those in the room into actual, even partial, agreement with one's own point of view, or even into acceptance of that point of view as potentially valid. Instead, I will argue, the addressed audience of the bureaucratic speakers is "the record," the official transcript of the hearing that will be preserved along with thousands of other documents relating to Avastin. The purpose of the hearing is therefore not to address other individuals or groups in the hope of changing their decisions or causing them to accept alternate rationalities or decision-making approaches, but only to make sure that certain claims are inserted into that record. All of this will suggest, finally, that the audience of bureaucracy is not the external public audience of democracy but the

internal audience of the bureaucracy itself. Bureaucracy speaks to itself, of itself, and for itself; its audience is itself, not “the people.” It is for this reason that it appears to be (and is) intractable to the kinds of intervention that the public speakers seek to effect.

Furthermore, it is for this reason that increasing transparency—increasing ability for the public to view the real workings of bureaucracy—leads to less, rather than more, trust in agencies such as the FDA.

In making this claim about the audience of bureaucracy, I will look not only for the presence of reformulations, but also their accumulated effects. Specifically, I will be looking for the achievement of Fact-Like Status for bureaucratic concepts of medicine, science, and public health. If a series of reformulations, in the course of a back-and-forth dialogue between two speaker groups or a response by one group to another’s statements, has the final effect of removing ambiguity, uncertainty, and possible openness to question from a claim, then that series of reformulations will be said to have achieved Fact-Like Status (FLS) for that particular claim. In the opposite case, if it has the effect of rendering an approach or claim permanently ambiguous or open to debate (permanently at least in the sense of no longer being valid within the context of the hearing), then it will be said to have achieved controversy around that approach or claim. Both of these terms—FLS and controversy—are adapted from and used in the sense intended by Latour and Woolgar (1979) in *Laboratory Life*, as described in the introduction. Not only is the movement from controversy to facticity in line with the concept of reformulations (both take note of slight changes in the phrasing of apparently identical factual information), but it also adds an important element to my readings of reformulations: if one of the primary discursive acts of the speakers is to reformulate one another’s statements into

forms that accord with their own rationalities and approaches to public health *without* any apparent regard for whether their interlocutors are in fact persuaded, then that suggests very strongly that the purpose of each speaker or group in the hearing is merely to have a particular form of the claim, a form of the claim commensurate with their desired approach to public health generally and the Avastin question specifically, cemented in the record as the final one.

Thus, I will argue, using reformulations series that tend either toward facticity or toward controversy, that the audience of the bureaucratic speakers in the hearing is, effectually, the record (and by extension future internal bureaucratic audiences) and not the physically present audience. I will also suggest that these speakers' purpose in the hearing is to achieve FLS for the bureaucratic approach to public health *because* their true audience is internal, and that the effect of the combined reformulations series is to achieve an overall FLS for the appropriateness and validity of the bureaucracy's forms and procedures. When one keeps in mind that bureaucracy is characterized by the interchangeability of individuals into and out of roles in which they enforce or enact those procedures, the very high value to bureaucratic speakers of constantly validating—achieving FLS for—those procedures is obvious. Moreover, by validating “for the record” the procedures by which their own decision was made, the bureaucratic speakers not only create a precedent on which future inhabitants of their own positions can stand, but also a circular justification for having used those procedures in the first place.⁹

⁹ In many ways, bureaucratic rhetoric is both similar to and driven by legal rhetoric, especially given that any bureaucracy, including the FDA, comes into existence by way of legislative documents that define its purposes and activities and outline (albeit often very vaguely) its proper procedures. The importance of the legal standard for withdrawal of accelerated approval, for example, becomes important in the Avastin hearing (see Chapter 3). As

Furthermore, this purpose of achieving FLS—not just for the FDA’s specific claims about Avastin, but for an attenuated bureaucratic concept of public health, medicine, and science in general—will also be demonstrated through a particularly interesting series of reformulations that occurs in a dialogue between the FDA’s official representatives (CDER, the Center for Drug Evaluation and Research, one of the “parties” to the hearing) and the “outside” advisory committee upon whose supposed objectivity the hearing depends (ODAC, the Oncologic Drugs Advisory Committee). In this reformulation series, the ODAC speakers reformulate questions previously asked by Genentech, not seeking further information, but to achieve controversy about the questions themselves by rephrasing them in ways that CDER can answer with much more certainty than they could answer them as phrased by Genentech. Much more will be said about this later, but the key here is that Genentech initially manages, through its reformulations of CDER statements and its own questions, to achieve a kind of facticity, or at least a reduction of controversy, for its own position. However, the next portion of the hearing, during which the “outside” advisory panel is allowed to question CDER, sees the ODAC speakers reformulating each of the questions Genentech achieved some facticity about, allowing the CDER speakers to reformulate their own responses in new ways, creating a final facticity for their approach. Not only does this strongly suggest

Greenhaw (1995) writes, “Law is the ongoing process of giving written authorities meaning in the context of disputes over what they mean in and for particular situations” (p. 866), a definition that accords with much of what the FDA does in this hearing. And Weber often overlapped the two terms, sometimes referring to bureaucracy as, for example, “legalistic.” However, although it would be interesting to investigate this overlap more fully, the purpose of the present project is to identify the effect of *bureaucraticity* on the public’s opinion of and response to the FDA—that bureaucraticity being more related to a circularity of self-supporting reasoning than to legalism per se. In fact, in this sense, the legal system is itself bureaucratic: self-supporting and reliant on the following of procedure for legitimation of decisions. Future projects will work to tease apart—and also connect—legal and bureaucratic rhetorics more fully.

that the “outside” committee is in fact to all intents and purposes an FDA committee, it also indicates how powerfully role (in this case, the advisory committee members’ *temporary* allegiance to the FDA) impacts rhetorical strategies and alliances in bureaucracy, overcoming even the committee’s apparent similarities to and membership in a professional medical community with the doctors who spoke as members of the public or as representatives of Genentech.

The next chapter will begin the analysis of the Avastin hearing by detailing the legitimizing rhetorics of the FDA and the public, as well as their inherent conflicts.

CHAPTER 3

LEGITIMIZING RHETORICS

Weber identified calculable rules as the primary defining characteristic of bureaucracy. However, just as Ceccarelli (2001) noted that sociologists of science did not “explain *how*” a scientific work “was able to have the influence it had” (p. 30), similarly, sociological concepts of bureaucracy describe and explain *what* bureaucracy is and does without fully explaining *how* it accomplishes its goals or enacts its characteristic effects. How, in other words, are the calculable rules of bureaucracy actually brought to bear on its objects and subjects? More importantly, for this project, how does a bureaucracy bring the objects and subjects of its rules *to accept and live by them*, given that bureaucracy is not purely an abstract concept but a means of governing, a way of controlling and driving action?

This is the role of the legitimizing rhetoric, a characteristic mode of language use that simultaneously expresses and enacts the types of evidence that will be considered compelling and valid within a system and denies as legitimate any other type. Bureaucracy’s legitimizing rhetoric is the linguistic expression of what Kalberg (1980) called “formal” rationality. Just as a rationality, in his terms, is a “regularity of action” (p. 1148), a legitimizing rhetoric is a regularity of discursive action, a pattern of speech. And the two—the pattern of action and the pattern of speech—are closely linked, in that

the pattern of speech expresses and legitimates the pattern of action (the rationality) and delegitimizes all others.

In its interaction with the public at the Avastin hearing, the FDA—primarily in the persons of members of its CDER committee—expresses itself through a rhetoric that perfectly aligns with Kalberg’s concept of “formal” rationality. In the course of the hearing, other, non-FDA speakers who use the same type of formal rhetoric are those who are perceived and responded to as legitimate (even if the FDA does not agree with them in the end). Genentech accomplishes this: while they do not win approval at this meeting, the FDA responds specifically to their claims, and the meeting paves the way for future bureaucratic interactions between the two entities. One might expect that a scientific research organization (such as a pharmaceutical developer), or a scientific research committee whose job is to provide expert advice to a political agency (such as ODAC), would speak with what Kalberg himself described as the rationality of science, the “theoretical” rationality. The fact that none of the scientists at the hearing uses this rationality is telling; it indicates a wide-spread influence of bureaucratic formalist rationalities—that is, rule following and calculation—over the other traditional understanding of science that involves invention, abstraction, and conceptualization.

Meanwhile, the type of rationality employed by the public is not only disregarded but explicitly delegitimized by the formally rational rhetoric of the FDA. The public, interestingly, speaks as with one voice, although the speakers do not generally know one another before the meeting, nor have they planned together in advance. In facing the FDA, they legitimize their own actions and beliefs, almost without exception, through a *practical-substantive* rhetoric. This practical-substantive rhetoric draws on and combines

two of Kalberg's rationalities. Practical rationality, he argues, "views and judges worldly activity in relation to the individual's purely pragmatic and egoistic interests" (p. 1151). A "practical rational way of life," he continues, "accepts given realities and calculates the most expedient means of dealing with the difficulties they present" (p. 1152). Not too surprisingly, the public speakers—most of whom are either cancer patients, family members of cancer patients, or clinicians working directly with patients to save their lives—address the problem of cancer very pragmatically, arguing for the importance of allowing Avastin even if only for the small group of patients who appear to respond positively to it.

A substantive rationality, on the other hand, assigns legitimacy to statements or actions "in relation to a past, present, or potential 'value postulate'" (p. 1155). As Kalberg notes, such a value postulate is "not simply a single value," but rather "implies clusters of values that vary in comprehensiveness, internal consistency, and content" (p. 1155). The value postulate at the center of the public's argument with the FDA is expressed in the joint concepts of *individualism* and *choice*.

The difference between the practical and the substantive rationalities—and the way in which they are used together and support one another—is clear for example in the statement, made by one of the cancer patients, that "The day may come when by [*sic*] body rejects these drugs, and I'll accept that. But I can't accept others rejecting it for me" (FDA, 2011a, p. 37). This same speaker then refers to the fact that while Avastin may have bad side effects, "breast cancer has only one, death." In other words, her argument draws its legitimacy and rationality from an interrelated pair of concepts: the *practical* realities that she faces as a breast cancer patient (her body may reject the drugs,

and cancer leads to death), and the values-based, or in Kalberg's terms *substantive* claim that she has the right to make her own choices. This powerful combination is reiterated by every one of the public speakers, whether these speakers are doctors, patients, family members, or representatives of organizations, and whether these speakers are in favor of Avastin or not (although most are).

In addition to providing examples of each of the types of legitimizing rhetoric—the formal rhetoric of the FDA and the practical-substantive rhetoric of the public speakers—I will break down in more detail the specifics of each of the types. Moreover, I will discuss the effects each of the types of rationality has on the hearing and its outcome. This will prepare the way for the next chapter's discussion of the ways in which the bureaucratic speakers address their audience and achieve their own, predecided outcome.

In this chapter, the analysis will focus primarily on two early portions of the hearing: the “affirmative presentation” by CDER and the statements by the public speakers. These are particularly important moments for each of the groups to employ their legitimizing rhetorics because they are the first opportunities that each group is given to speak (and therefore their first and best opportunities to lay out the basis on which the hearing's decisions will or should be made). Moreover, the public statement segment that opens the hearing is the only time during which the public is allowed to speak, and the affirmative presentation by CDER follows directly after it, making that portion of the hearing particularly important for CDER in terms of opposing the public's compelling practical-substantive rhetoric with its own formal one. Obviously, it will be

impossible to note or analyze every instance of each type of legitimizing rhetoric; rather, representative examples will be analyzed in detail.

We will begin with a discussion of the four primary rhetorical expressions of the FDA's formal rhetoric (two types of definitional statements and two types of procedural statements) and then move on to analyze the practical-substantive rhetoric of the public, with special emphasis on the ways in which the FDA's presentation specifically opposes and thwarts it.

Formal Rhetoric as the Legitimizing Rhetoric of Bureaucracy

The formal rhetoric of the FDA is the linguistic enactment of the calculable rule basis of bureaucracy. Essentially, every statement made by a speaker for the FDA makes use of this type of legitimizing rhetoric to implicitly justify, not the specific decision made in the Avastin case, but a bureaucratic, rule-based approach to public health generally. In practice, this justification is enacted through two main types of statements: definitional statements and procedural statements. Both types of statements are rule-oriented. Definitions serve to delimit the meanings of a word, term, or concept, allowing certain meanings and disallowing others (for example, when the FDA speakers seek to define "quality of life" in purely measurable terms, a definition that would automatically disallow the patients' statements that quality of life is individually and subjectively defined). Procedural statements similarly allow and disallow, but rather than allowing and disallowing *meanings*, they allow and disallow *actions* (for example, when the FDA speakers work to reduce the phrase "scientific evidence" to a set of claims based on a limited number of bureaucratically-approved experimental and analytical procedures). Through both its definitional and its procedural statements, in other words (and these

make up almost the entirety of all statements made by FDA speakers), the FDA constantly both uses its rules to “fence in” and “fence out” what is allowed and disallowed, and simultaneously reifies and supports the rules themselves by defining them *as* what is allowable. It is a circular, self-supporting rhetoric that creates a tight and nearly unassailable space in which only the FDA can make rules, and only rules can guide decisions.

Each of these types of statements can also be further broken down. Of definitional statements, the FDA tends to make two types—calculable and expertise-based—and of procedural statements, two types are also used—statements about experimental procedure and statements about decision-making procedure. All of these reflect concepts central to the formal rationality of bureaucracy as laid out by Weber and Kalberg.

Definitional Statements and the Circular Legitimation of

Calculability and Expertise

Calculable definitions are those that define a word or concept in terms of calculations, while expertise-based definitions are those that define a word or concept on the basis of what experts say about it. Another way to phrase it would be to say that calculable definitions are those that reduce the meaning of a term—generally a contested one—to only that meaning of the term that is calculable or relies on calculations, while expertise-based definitions are those that reduce the meaning of a (generally contested) term to only that meaning of the term that is accepted or stated by (particular) experts.

For example, one of the consistently controversial terms in the hearing is the term “benefit.” The public attempts to open the definition of benefit to allow many types of

outcomes to count: feeling better, being hopeful, and spending additional time with one's loved ones, for example. As soon as CDER is given the opportunity to offer its "affirmative presentation" (its first turn to speak, during which it may present its own position without questions or interruptions), its first move is to reduce the definition of "benefit" to only those meanings that can be mathematically and statistically calculated. "In determining the net benefit of the drug," Dr. Pazdur says (Dr. Pazdur is the head of the CDER committee), "we must assess the type and the magnitude of the benefit, and weigh that information against any safety concerns or risks" (FDA, 2011a, p. 130). Already he is defining benefit by only two terms, "type" and "magnitude," of which one is explicitly a calculation. Very quickly, "type" is lost and the definition is reduced to questions of magnitude—as calculable through statistics—only. In the very next sentence, he says that "[a]ny improvement in overall survival is generally considered the gold standard endpoint in oncology trials" (130), a statement that places the tightest possible limitations on the concept of "benefit," reducing it such that only an increase in overall survival (that is, a measurable increase in the number of average days or months lived) truly counts as a benefit.

Expert-based definitions are similar in that their purpose is to *reduce* a concept's definition to the point at which only expert definitions (and, as we will see shortly, only the FDA's experts' definitions) count as valid. For example, in the same opening remarks during the affirmative presentation, Dr. Pazdur makes use of expert-based definitions of "benefit." Not only does he refer to overall survival as "the gold standard" (implying that it has the imprimatur of the experts), but he more explicitly argues for a definition of benefit reduced only to the meaning used by bureaucratic public health

experts. “In 1999,” he says, “ODAC recommended that we require drugs to demonstrate an improvement in overall survival for approval for first-line metastatic breast cancer” (p. 130). Just a few paragraphs later, he “fences out” the public’s definition of benefit—Progression-Free Survival or PFS—through the same maneuver: “CDER has consistently emphasized that a demonstration of statistically significant improvement in PFS may not translate to a favorable risk-benefit decision” (132). Only those benefits, in other words, that are defined by calculation *and* that are moreover defined by the specific calculations that FDA-approved experts would use, count as valid definitions.

In all cases, the terms to be defined are those at the very heart of the debate between the public and the FDA—terms having to do with what counts as an “outcome” for the purposes of health decision making. Terms such as “risk-benefit ratio,” for example, as well as such seemingly fundamental concepts as “survival,” are defined and redefined throughout the hearing as the FDA seeks to narrow their possible meanings only to those that support both the already-determined Avastin decision and the bureaucratic approach to public health.

However, what is most interesting about all of these definitions is that they *appear* to base their validity on calculation but are in fact not as rule-based as they seem. On the surface, for example, a ratio or a magnitude is a mathematic concept that appears to be a pure calculation. In each case, however, an apparently calculable term is explicitly justified on the basis of its calculability (because this is the basis of bureaucratic rationality) but is in fact finally placed on the basis of expertise, not calculation.

The constant definition and redefinition of risk-benefit ratio is a particularly visible example of this process, as risk-benefit ratio is always claimed by the FDA as *the* basis for decision making. For example, one FDA speaker appears frustrated near the end of the first day by the need to repeat what (he implies) is a simple concept: “As I stated before, for the fifth time, we are not approving a drug on a hazard ratio. We are approving it on a risk-benefit ratio” (p. 251). And again, two sentences later: “One has to take a look on an individual basis of the risk-benefit ratio of that drug” (p. 251). What is fascinating here is the double face. On the one hand, this speaker constantly refers to the importance of a calculable outcome—the risk-benefit ratio—in making the decision. At the same time, however, he utterly derides (and he does this throughout the two days) another equally calculable outcome, the hazard ratio.

What he is doing exemplifies precisely the circular legitimizing rhetoric of the bureaucracy that relies on the two complementary elements of formal bureaucratic rationality: calculability and expertise. Driven to explain himself further, he says that “The bottom line is we don’t approve a drug on a hazard ratio. We don’t approve a drug on median differences. We approve the drug on a *clinical determination* of the risks and the benefits of the drug” (p. 248, emphasis mine). That last sentence perfectly blends calculability (risks and benefits) and expertise (clinical determination) in a way that the FDA speakers rely on throughout the hearing. The difficulty for the FDA is that whenever they present calculability as the pure basis of health decision making, they are immediately contested by Genentech’s representatives, who have come prepared with their own calculations. The FDA favors the risk-benefit ratio, while Genentech favors

hazard ratios (among other outcomes that did show benefit for Avastin), and both have been used in previous decisions by various public health agencies.

In fact, in the hearing itself, both Genentech and the public speakers refer to previous cancer drug decisions that were based on hazard ratios or on various other measurements. For example, one ovarian cancer patient advocate says that she is speaking at the hearing because “clinical trial data for ovarian cancer are not dissimilar to those with metastatic breast cancer” (p. 47), yet at the moment, Avastin is approved for ovarian cancer and not for breast cancer—based on these “not dissimilar,” in fact almost identical, findings. What is particularly telling about this is that the FDA will not allow any other parties to make comparisons to any of its previous decisions; in fact, it actually *rules out* any comparisons to its own previous findings. For example, Genentech tries to point out that the Avastin data are similar to the data used to approve other cancer drugs, saying, “Well, CDER has also compared the Avastin data at different times to Gemzar and Herceptin data; is that correct?” Ms. Bandel of CDER responds not by answering the question, but by saying, “I would just like to remind everyone that according to the ground rules set out in the notice of hearing”—which of course are set by the FDA—“decisions regarding other products would not be considered relevant in this proceeding” (p. 218). In other words, any reference to the fact that the FDA has approved other drugs on the basis of data almost identical to that which it is using to reject Avastin *is not allowable* as evidence in the hearing. More than once, when confronted with what appear to be inconsistencies in its own methods of measuring and approving outcomes, the FDA refers back to the procedures and rules it has set up to ensure that such comparisons cannot even be made in the hearing. The FDA could not make it more clear that the

actual scientific validity of particular endpoints is not in fact the issue or the point; the point is that the bureaucratic decision has already been made and that the only allowable measurements and calculations are the ones that support it.

Similarly, other speakers note that while the FDA is claiming that a moderate increase in PFS is not sufficient to approve Avastin, the same or similar levels of PFS improvement have been accepted in previous cases. As one speaker put it:

You know the efficacy of first-line Avastin from the three randomized trials.

You know progression-free survival is longer. You know the objective response rates are higher, and yet you the FDA have approved other drugs with only progression-free survival without overall survival. You approved Ixempra. You approved Tykerb. (p. 50)

Again, references to the FDA's previous decisions are disregarded as out of bounds according to the rules laid out for the hearing. Perhaps most telling is Genentech's continued reference to the FDA's own pre-approved endpoint for the Avastin studies. Every study conducted for approval by the FDA has to meet endpoints that have been predecided by the FDA and the pharmaceutical maker. In this case, Genentech argues (using documents provided to them by the FDA itself) that those endpoints have been met. As one Genentech representative puts it, "the AVADO and RIBBON 1 studies met their prespecified endpoint with hazard ratios less than 0.7, and as such do not invalidate the findings of E2100" (FDA, 2011b, p. 8). Again, Genentech notes:

The conclusion drawn by CDER that the subsequent studies did not demonstrate meaningful benefit was based on medians. Solely focusing on the median differences is flawed, as they can under or at times overestimate the true treatment effect. In addition, this focus on median differences as the primary method of assessing magnitude of benefit appears to represent a change in CDER's thinking since 2008. (p. 13)

2008 was when the FDA originally presented the required endpoints for Avastin’s confirmatory studies—which prearranged endpoints Genentech argues the drug did in fact meet. In other words, it is made clear throughout the hearing that other (international) analogous public health bodies, previous studies and approvals by the FDA itself, and in fact the FDA’s own predetermined outcomes requirements for the Avastin confirmatory trials indicate that the evidence provided by those trials should have been sufficient. The FDA, however, not only indicates that it will not consider such comparisons; it actually rules them disallowed through the entire hearing.

The issue here is not which of these is valid or which types of endpoints have been used in which FDA trials. The issue is that determining which endpoints are truly valid at predicting the usefulness of a drug is far more subjective, questionable, and complex than the FDA is willing to admit here. There are potentially multiple measurements upon which the decision could have been based consistent with previous FDA studies, yet the FDA speakers at the hearing put credence in only one measurement because a decision about Avastin has already been made before the hearing begins (as we will see more clearly in Chapter 4). In other words, when faced with multiple calculations that support different outcomes, the bureaucracy ensures its desired outcome by allowing only those measurements that lead to that outcome—even when other recognized bodies and its own decisions on other drugs seem to contradict that narrowness of focus. It justifies this by drawing on its second support, expertise: the “clinical determination.”

Genentech presses the FDA hard, claiming that the agency will not “communicate what measure of magnitude it’s going to emphasize” (p. 248)—essentially undermining

the FDA's own claims to calculability, consistency, and rule basis. If the FDA cannot provide a consistent set of rules for what outcomes will be acceptable as evidence, Genentech implies, then why are calculable outcomes held out as the standards? The FDA replies by repeating that its decisions *about* calculability (about which calculations will count) are based on expertise: "The situation here is, again, it's a clinical decision that we're making as far as a risk-benefit decision" (p. 250), and again, "At the end of the day, you have to show a clinically meaningful impact in the risk-benefit analysis" (p. 261).

However, as one might expect, the reliance on clinical judgment opens the door for other clinicians (some of the Genentech speakers, for example, and those of the public speakers who are practicing oncologists) to make their own, independent decisions that differ from the FDA's. So the agency supports the expert judgments of their own experts over the judgments of others through the particular rhetorical maneuver they use again and again: circularity. In this case, they use a circular reference to calculability. When Genentech opens the door for alternate interpretations on the basis of the very thing—clinical judgment—that the FDA used to support its finding, the FDA responds by arguing that "The statute and the regulations authorize CDER to withdraw approval under specific circumstances [...] and] we've met the legal standard for withdrawal" (p. 262). In other words, there are specific and calculable rules that are *not* open to interpretation that the agency adheres to, and *that* is the basis of the decision.

Genentech presses again, asking what the FDA's "concept" of that standard is, again using the FDA's own insistence that it is clinical judgment—that is, *interpretation* of the calculable standard—that matters. One of Genentech's representatives asks

whether there are “legitimate alternate views of the data,” for example the views of other groups of experts, the regulatory bodies of other countries and the EU, some of whom approved Avastin for breast cancer on the basis of the same evidence that the FDA is using to withdraw the approval. In response, the FDA again replies by justifying itself on the basis of calculability, repeating several times that “the benefits don’t outweigh the risks” and that “that’s the regulatory and legal standard for approval” (p. 268). In other words, not expert judgment and interpretation but hard-and-fast, calculable rules are the basis of the decision.

Over the course of this single exchange—and in a pattern that repeats itself again and again throughout the hearing—the FDA offers what appears to be a calculable rule as the basis for its decision making, and then when presented with contrary but equally calculable outcomes (hazard ratio, for example, as opposed to risk-benefit ratio), they offer expert judgment as the basis for deciding between such rules. However, when pressed again on the basis that other, equally expert judges have come to different decisions about the same data, the FDA retreats not only to calculability as the basis for its expertise, but to the *same* calculations (in this case, risk-benefit ratio) that were the subject of the debate that required expert judgment. In this way, through circular definitions of calculable rules in terms of expertise and expertise in terms of calculable rules, the FDA maintains not only legitimacy for its own already-made decisions (the withdrawal of Avastin’s breast cancer indication, in this case) but also, and more importantly, for itself as the sole decision maker and its bureaucratic methods of decision making as the only legitimate ones. This is the way in which definitional statements—statements that seek to narrow the acceptable definitions of clinical outcomes to both

support the calculable rule basis of bureaucracy and to draw support from it—enact Kalberg’s formal rationality through patterns of rhetorical action.

Procedural Statements and the Attenuation of Science and Medicine

Similarly, the FDA uses its procedural statements to legitimize the bureaucratic, public health approach to health decision making as much as to legitimize the Avastin decision. Where definitions seek to delimit allowable and not allowable meanings, procedural statements seek to delimit allowable and not allowable actions. And in the FDA’s case, procedural statements are used to circumscribe two kinds of action: experimental actions and decision-making actions. Just as calculable and expert-based definitions were mutually supporting and interrelated, so too are the two kinds of procedural statements. As the FDA delimits those experimental procedures that will be accounted valid in the research it will accept, it simultaneously delimits the decision-making procedure (that is, the procedure of the hearing itself and the stages of action leading up to it) such that only decisions *based* on those experimental procedures will count as legitimate. In so doing, the FDA effectively limits science and medicine themselves to only those elements of scientific practice that are rule-based, repeatable procedures (i.e., bureaucratic science), delegitimizing other concepts of both science and clinical medicine that might value insight, innovation, or art—despite the fact that both scientists and medical practitioners have lauded these elements of their respective professions for as long as they have existed (Duke, 1972; Howe, 2004; Groopman, 2007; Shapin, 2008). We will discuss this larger-scale effect of bureaucratic rhetoric on the professions of science and medicine in more detail in the conclusion; here, we will focus on the specific rhetorical strategies by which the FDA legitimizes a particular procedural

concept of experimental science and then delimits the procedures of the regulatory process such that only the procedural concept of science is valid in the hearing.

The CDER speakers spend a great deal of time during their affirmative presentation making statements that delimit what counts as valid, acceptable experimental procedure. Dr. Pazdur begins with the claim, in the third paragraph of his statement, that regulatory decisions must be based on scientific evidence. However, he does not allow that relatively generic (and, as we will see, highly polysemous) term go undefined for long. In the next sentence, he claims that “our regulatory decisions are based on data from adequate and well-controlled clinical trials” (FDA, 2011a, p. 126), a definition of “scientific evidence” that already begins to narrow “scientific” to “procedurally correct.”

Dr. Keegan, another member of CDER’s speaking team, continues this procedural narrowing later in the affirmative presentation (after a long discourse by Dr. Pazdur on regulatory and decision-making procedure, which I will describe below), outlining precisely why the procedural approaches of studies suggesting Avastin to be beneficial are not valid. Moreover, in keeping with Weber’s concept of “the record” as the key reference point in all bureaucratic decision making, Dr. Keegan constantly refers to various documents produced by the FDA that outline correct experimental procedure. As with the definitional statements, this is circular: the FDA speakers are arguing for the validity of their own approaches on the basis of documents they themselves have written—which in turn are based on FDA arguments in favor of those approaches, and so on. Dr. Keegan specifically takes on Genentech’s claim that the FDA should allow Avastin to remain available, with the breast cancer indication, while further research is

conducted. Genentech's argument is based on their statement that at least one of their existing studies supports Avastin's benefits for breast cancer patients.

The ways in which Dr. Keegan responds to Genentech's claims exemplifies the experimental procedural statements that support the bureaucracy's particular approach to public health throughout the hearing. She begins by stating that "CDER has consistently communicated that the magnitude of the progression-free survival effect is critical, that the E2100 [Genentech's supporting study] results are not representative of Avastin's true treatment effect. That is, the E2100 results are an outlier" (p. 173). This statement accomplishes two things. First, it supports the FDA speakers' often-repeated insistence that "the totality of the data" must be considered in evaluating experiments, never one study individually. And second—and more importantly—Keegan's statement justifies the FDA decision on the basis that *the FDA has stated, and continues to state, what it considers as experimentally valid*, that is, "the magnitude of the progression-free survival effect" (and it is no coincidence that the experimental procedure the FDA approves is also reliant on calculability). What is interesting here is that there is no attempt even to appear to step out of the self-justifying circle: the particular experimental procedures that will be deemed valid in the hearing are deemed so *not* because they may or may not be the most valid, the most widely recognized by scientists, but only because they have been expressed by the FDA and the FDA will accept only what it has previously expressed.

After a brief discussion of the FDA's belief that the new research will not confirm the E2100 study, Dr. Keegan returns to the same argument. "I will begin," she says, "by describing the manner in which CDER has consistently communicated to Genentech that the magnitude of the progression-free survival effect is a critical aspect" (p. 174). Again,

the argument does not address whether the magnitude of PFS has been determined by independent scientists to be the most important factor; rather, what is important is that it is has been the stated procedure of the FDA to focus on that factor in evaluating the breast cancer indication for Avastin¹⁰. Consistency with its own current record and consistency with the narrowly defined experimental procedures and outcomes outlined *in* that record are the only acceptable measures of validity. Dr. Keegan continues in this vein, arguing that CDER's standards "have been consistent throughout its review of Avastin's metastatic breast cancer application" (p. 174), then enumerating all of the dates on which the communication was made: "including on October 28th, 2004, December 5th, 2007, and on February 22nd, 2008" (p. 175). Furthermore, she goes on to say, "this general policy is clearly stated in FDA's May 2007 guidance for industry on clinical trial endpoints for the approval of cancer drugs and biologics" (p. 175). After continuing to elaborate the ways in which Genentech was specifically informed of acceptable outcomes, she becomes even more explicit about the FDA's insistence on limiting which experimental procedures will be accepted: "CDER communicated that there are three acceptable ways to confirm benefit," she notes (p. 176), making it clear that what is important is not that these are necessarily the best or the most scientifically valid but that they are the *FDA-accepted* procedures.

Dr. Keegan also provides, later in her statement, a long list of those accepted or required procedures Genentech either did not perform or did not perform to FDA-

¹⁰ It was mentioned above, but is important enough to emphasize here, that a bureaucracy need not maintain rules that are consistent from one decision to another—only that the appearance of consistency within a particular record is maintained. This is one of the main reasons the FDA does not allow references to any of its other decisions in the hearing, even other decisions about breast cancer drugs or other decisions about Avastin.

accepted standards or expectations. Again, the focus is on whether the drug company conformed to FDA's standards of acceptability, *not* whether the studies could be seen by other objective, scientific observers as indications that Avastin is valuable or beneficial. (As Genentech points out, these same studies *were* in fact viewed as acceptable by other regulatory bodies with other standards, a fact CDER consistently negates as irrelevant, demonstrating further that objective identifications of Avastin's benefits are not only probably impossible to actually ascertain but in fact are not the point at issue, the point at issue for the FDA being whether Genentech followed experimental procedure guidelines laid out in the particular bureaucratic record relating to the Avastin indication for breast cancer). Keegan notes that "clinical course and outcomes of proteinuria were not collected in most clinical studies submitted by Genentech, and therefore the consequences of Avastin-induce renal toxicity remain poorly characterized" (p. 193). Similarly, and even more damning, "the criteria for mild and moderate hypertension in the NCE CTCAE versions 2 and 3 are inconsistent with practice guidelines for the treatment of hypertension" (p. 195) and are similarly "poorly characterized" (p. 196). The question here is not, in fact, whether proteinuria or hypertension occur—or whether these are in fact highly acceptable side effects for the vast majority of poor-prognosis breast cancer patients, as those patients themselves try to argue during the public speaking period—but whether those potential side effects were properly characterized and measured according to FDA-acceptable standards.

Perhaps most interesting is the presentation by Dr. Pai-Scherf, a medical officer for CDER. Speaking directly after an FDA lawyer who outlines the legal standard for withdrawal, Dr. Pai-Scherf's role is to present a "review" of the clinical data. His

presentation is almost wholly consumed, however, with a review of the procedural issues, especially what the FDA perceives as procedural problems in the Avastin experiments and the presentation of data. After a brief historical overview of the Avastin approval process, he begins to provide a great deal of detail about the experimental procedures used by Genentech and the procedural responses enacted by the FDA in response:

After review of the submission, CDER issued a filing deficiency letter. Key issues are listed on this slide. Subsequent to the filing deficiency letter, Genentech conducted a data clean-up and retrospectively collected radiographic scans to perform an independent blinded review of the progression events. (p. 146)

In effect, he is repositioning the debate, moving away from a discussion of what the data mean, whether they indicate benefit, and what decision should be or should have been made, to a narrowly-focused discussion of experimental procedure issues on the part of Genentech—a discussion CDER cannot lose specifically because the only procedures allowed by the bureaucracy are those it has designed itself, and the only speakers authorized to determine whether approved experimental procedures have been achieved are the bureaucratic ones. From this point forward, Dr. Pai-Scherf focuses a great deal of attention on the experimental procedures of the studies, noting for example that CDER “has concerns with the quality of life data” because “[t]he open-label design has a high potential for bias, there were significant missing data, and we have concerns regarding the imputation methods used in the analysis” (p. 147). Furthermore, wherever uncertainty exists around the meaning, outcome, or importance of a piece or type of data, Dr. Pai-Scherf reduces that uncertainty and debate to a question of pure procedure, noting for example that there was “only one singly open-label study with positive data to support approval” (p. 148), a statement that allows him to move the entire question from one of

whether the data do, in fact, support approval to whether there were *sufficient* data, *correctly collected*. In particular, the strongest supporting study, E2100, is always addressed by Pai-Scherf in terms of procedure; he notes again and again that the study “had shortcomings and inconsistencies,” that “the study has to be powered for survival” (a contested point in itself), and that other studies did not confirm it because of their “trial design” (pp. 149-150).

The key point here is that the FDA speakers consistently make statements that indicate that the key question in the hearing is in fact *not* whether patients will benefit from Avastin (“benefit from Avastin” being itself a vague and highly contested concept), but whether correct procedures have been followed in the conducting of experiments. Moreover, the constant conflating of “scientific evidence” and “science” with this limited, narrowly-defined notion of rigidly defined experimental procedure is troubling because of the vast influence the FDA and other bureaucratic agencies have on experimental science, a field that has historically been defined both by experimental design and by innovation and intuition.

The second type of procedural statement—and the final of the four types of statements in this hearing that represent the formal legitimizing rhetoric of the bureaucracy—is the decision making procedural statement. As with experimental procedural statements, these attempt to delimit and narrow the acceptable range of actions, except that in this case, the actions to be limited are those associated with public health decision making rather than scientific experimental design. Just as the experimental procedural statements showed the bureaucracy to be far more concerned with *how* scientific results were arrived at than *what* the results were or how they might

affect patients—whether the drug had, in fact, “benefits” of some kind or not—the CDER speakers discuss decision-making procedure not in terms of whether the correct decision has been made, or the correct or most appropriate decision-making procedures adhered to, but whether the procedures outlined by the bureaucracy in the past have been consistently followed in this case. This limits “decision making” to those processes already laid out in the record, just as the experimental procedural statements limited “science” to those experimental processes predetermined by that same record as valid.

A typical example of this reference to the record to limit the scope of valid decision-making procedures is evident early in Dr. Pazdur’s portion of CDER’s affirmative presentation. He notes that in July of 2010, CDER “sought expert advice from ODAC in reviewing and interpreting the available data for Avastin in breast cancer. Following a careful review and discussion of the available data, the members of the committee recommended nearly unanimously, nearly 12 to 1, that the indication for breast cancer be withdrawn” (p. 136). Notice again that the focus is not on whether the committee made the correct *decision*, but whether the decision was arrived at through the proper, bureaucratically-approved procedures.

Dr. Pazdur continues in the same vein later in the same speech, noting that the Agency is required to “show an appropriate degree of flexibility in making new promising drugs available” and that “[t]he accelerated approval regulations [...] provides us that flexibility” (p. 137). This sets up a lengthy discussion by the next speaker, Ms. Brandel, the lawyer for the FDA’s Office of Chief Counsel, who continues the same theme, detailing the “legal framework of accelerated approval” (p. 138). She discusses the “two statutes relevant to this proceeding,” the FDA regulations that apply, the “two

mechanisms of approval of a biological product,” and the details of the Food, Drug and Cosmetic Act that lay out the legal aspects of the accelerated approval pathway (p. 139). Throughout, her focus is solely on the record—the existing and explicitly written rules by which decisions about pharmaceuticals may and must be made. The continual reiteration of the metaphor of the “pathway” to approval is telling. The key to acceptance of a drug within the bureaucratic public health framework is to follow the preapproved path prescribed in the record; all other considerations are detours and thus outside of consideration.

Ms. Brandel continues for nearly six transcript pages describing in detail the allowed decision-making procedures, essentially outlining, before the other CDER speakers fill in the clinical data, the only acceptable means by which those data may be judged. Interestingly, nowhere does she make specific references to the clinical outcomes of the trials themselves. Rather, she lays out the rules by which a negative decision (withdrawal) must be arrived at, continually implying, but not stating, that Avastin *must* have failed to meet acceptance criteria, since its approval was withdrawn. At the very end of her statement, she concludes by stating:

As you can see on this slide, the regulations authorize FDA to withdraw accelerated approval if, among other things, a post-approval study fails to verify the drug’s clinical benefit, or other evidence demonstrates that the drug is not shown to be safe or effective. Either one is grounds for withdrawal.

As will be explained by CDER scientists, both of these criteria are met here. That means that the legal standard for withdrawal has been met¹¹. (p. 144)

¹¹ Again, the overlap of legal and bureaucratic rhetorics is obvious here. And the constantly looming possibility of Congressional review does play an outsized role in FDA decision making. As one former FDA commissioner put it, “In all of the FDA’s history, I am unable to find a single instance where a Congressional committee investigated the failure of FDA to approve a new drug. But, the times when hearings have been held to criticize our approval of

Again, what appears to be the very point at issue is treated as secondary: whether the drug in fact has benefits, whether those suffering from breast cancer should be allowed to take the drug, what the data mean or imply—all of these questions, which might appear to be central (and which the public, as we will see, attempts to make or keep central) are subordinated to questions about whether the approved procedure has been followed.

Furthermore, this focus on procedurality allows the FDA to continually *presuppose* that the benchmarks for decision making—the benchmarks for early withdrawal or for rejection—have in fact been met, either by simply noting what those benchmarks are or embedding presuppositions (Levinson, 1983)¹² in larger statements about the benchmarks. For example, Dr. Pazdur says: “Because the pre-selected confirmatory trials have failed to verify the clinical benefit, and the available data do not support a favorable benefit-risk balance for Avastin in breast cancer, it is not appropriate to continue accelerated approval while Genentech tries to conduct another trial” (p. 137). The long “because” phrase presupposes that the trials have, in fact, failed to verify the clinical benefit, when this is precisely one of the key points at issue with Genentech. By

new drugs have been so frequent that we aren’t able to count them. The message to the FDA staff could not be clearer. Whenever a controversy over a new drug is resolved by its approval, the Agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made” (qtd. in Hawthorne, 2005: p. 28). Although the FDA also lives with the possibility of public outcry against negative decisions, in other words (especially since the AIDS crisis of the 1980s), the real fear in the agency is about Congressional oversight. This is another external *political and legal* influence on the FDA that would bear investigation in future studies, in which I hope to tease out further the interactions between bureaucratic rhetorics and procedures and the external political and legal influences on them. Here, though, the focus is the interaction between bureaucracy and the public.

¹² A term very familiar to rhetorical scholars, a “presupposition” is something the speaker takes for granted when making an utterance (Grice, 1975) and which is therefore embedded in the utterance. Or as Mazid (2007) puts it, a presupposition can be defined “by means of the distinction between what is treated as ‘given’ and what is treated as ‘new’ in a linguistic exchange; what is presupposed seems synonymous with what is given or agreed upon” (p. 354). The key here is that a presupposition makes it *seem* that some claim is given or has been agreed upon.

couching the argument in terms of the procedural benchmarks, however, the FDA speakers can embed presuppositions that those benchmarks have been met, avoiding exactly the debate about the meaning of the data that Genentech and the public speakers wish to have.

Dr. Pazdur is certainly not the only CDER speaker who does this. Dr. Pai-Scherf, for example, argues that the data demonstrate that Avastin does not provide a clinical benefit—but not by detailing the data. Rather, he notes that “[t]he committee was near unanimous in their vote” about the risk-benefit ratio, that “[t]he committee was unanimous in their vote” about the confirmatory trials, and that “the committee were near unanimous in recommending that the indication for treatment of metastatic breast cancer be removed from the Avastin label” (p. 167). Here we not only see, again, the superseding of data by the rules of approved decision-making procedure, but also the way in which procedural statements contribute to the enclosed circle of bureaucratic formal rhetoric in the same way definitional statements do. Pai-Scherf is arguing that the drug can only be approved if the data demonstrate that the drug is more beneficial than harmful, an appeal to scientific experiment. At the same time, he is claiming that the only approved method for determining whether the data demonstrate a benefit is through voting by the FDA committee. The problem is that the FDA committee is not only the same one that determines the approved decision-making process but is *also* the same one that determines which data are collected and how they are collected and analyzed.

As we will see in the next chapter, the closed circle of FDA decision-making rationality is not only obvious in its expression in a formal legitimizing rhetoric of definitional and procedural statements at the hearing: it is also obvious to the members of

the public affected by it. In fact, its rhetorical expression at the hearing is particularly important for the patients who have come to speak as representative members of the affected public because that rhetorical expression immediately follows, and expressly delegitimizes, the rhetoric of the public speakers themselves, which is founded on the substantive and practical rationalities encapsulated by Kalberg as values-based and interest-based. As we will see in the following section, the public speakers' legitimizing rhetoric is in direct opposition to the bureaucracy's. Although the public speakers' presentation occurs at the beginning of the hearing, I am examining it second to show more explicitly its direct opposition to the bureaucratic discourse.

The Public's Practical-Substantive Rhetoric: Individualism, Choice,
and Democratic Health

At the Avastin hearing, the FDA is clearly the authoritative participant. It determines the rules and regulations (or at least interprets those handed down by Congress); it sets the procedures for the hearing; it determines the processes whereby drug companies and the public may petition it. For this reason, the FDA can, through all of its official spokespersons at the hearing, speak almost entirely in definitional and procedural statements. Its statements make clear, unassailable (or apparently unassailable) statements about how things *are*. In other words, its statements need not even claim that risk-benefit analysis *should be* defined in a particular way, but simply state the definition of a risk-benefit analysis and apply that definition as the unquestionably correct one. The public, however, is very much in the "one-down" or disenfranchised position at the hearing. For this reason, rather than making direct claims

about definition or procedure, the public speakers make appeals to the more powerful bureaucratic speakers and institutions.

Just as the definitional and procedural statements of the bureaucratic speakers reflect and expose their underlying legitimizing rhetoric based in a formal rationality (in Kalberg's terms), the public's appeals expose their directly opposed legitimizing rhetoric, based in a practical-substantive rationality. Where formal rationality is rule-based—and particularly based on calculable and expert rules applicable to homogenized populations—both practical and substantive rationalities are subjective and based on individual outcomes and beliefs. As Kalberg (1980) puts it, a practical rationality is one based on “interests” and includes “every way of life that views and judges worldly activities in relation to the individual's purely pragmatic and egoistic needs” (p. 1151). A practical rationality, he continues, “accepts given realities and calculates the most expedient means of dealing with the difficulties they present” (p. 1152). For the public speakers at the Avastin hearing, the “given reality” with which they must find the most expedient means of dealing is disease; for these speakers, who are all cancer patients, family members of cancer patients, or clinicians who work directly with cancer patients, the reality with which they are presented is the immediate likelihood of death. As a result, a purely pragmatic approach to cancer, one in which the measurements are any signs that improvement has occurred and death staved off even for a day, underlies every statement they make. One kind of appeal reflects this practical rationality particularly strongly during the public speakers' presentations: claims that frame benefits, outcomes, and side effects as purely personal considerations to be weighed and decided on only by the individual affected by the realities of cancer.

However, their statements are not all based on a practical rationality. Although Kalberg does not mention the possibility, clearly a combination of rationalities may be operating in a given community simultaneously, especially if they work together to legitimize a certain outcome or approach, as the practical and substantive rationalities do in this case. The second rationality by which the public speakers legitimize their own approach to the Avastin decision is the substantive or “values”-based rationality. Kalberg notes that substantive rationality “orders action into patterns [...] in relation to a past, present, or potential ‘value postulate,’” which is “not simply a single value,” but rather “entire clusters of values” allowing for “value-rational action” (p. 1155). Interestingly, Kalbger further notes that “[f]ormal rationalities have stood in the most direct antagonism to many substantive rationalities” (p. 1157), a claim that makes sense given that formal rationality is characterized by calculability and rule-based action, whereas substantive rationality legitimizes actions based on their coherence with a set of values and beliefs that may be highly subjective and are always dependent on “an individual’s implied or stated, conscious or unconscious, preference” (p. 1156). For the public speakers at the Avastin hearing, the “value postulate” on the basis of which they believe decisions should be made is that of choice; every one of these speakers (notably even those who agree with the FDA about withdrawing Avastin) legitimizes his or her desired decision upon the basis that cancer patients should be allowed to choose among—to have access to—as many options as possible. Appeals based on this substantive rationality are made throughout the public speakers’ presentations, focusing around the ongoing claim that the most important value in public health is *access* to as many choices as possible in managing disease.

In short, the legitimizing rhetoric of the public speakers is a practical-substantive combination by which the reality of death overrides all other considerations, such that *any* means of dealing with that reality is valid—and such that those dealing with it should have access to all possible options, no matter what their “calculated” risks and benefits. Interestingly, the public’s legitimizing rhetoric is fundamentally *political*—a set of appeals based on individuals’ pragmatic needs and group values and beliefs—in direct opposition to the fundamentally *bureaucratic* legitimizing rhetoric of the FDA, yet another indicator that the conflating of political and bureaucratic speech overlooks key differences and hides at least one of the most powerful reasons behind the apparently paradoxical result that increased government transparency has correlated with decreased trust. If the public was previously exposed only to the political rhetoric of the members of Congress who make broad health policy, they may well have been under the impression that public health decisions were made on the same basis—a political basis in line with the public’s own practical-substantive rationality. The more the public is confronted with the reality that the actual public health decisions made by the government are in fact made in accordance with bureaucratic rationalities of calculable rules, the more that public may oppose institutions it previously supported. In any case, the legitimizing rhetoric of the public speakers in this particular hearing is fundamentally opposed to the legitimizing rhetoric of the bureaucracy they address.

Practical Rationality: Confronting the Realities of Disease and Death

If a practical rationality involves dealing with the realities of life in a pragmatic way and identifying and using the most expedient means for handling those realities, then the reality that drives the practical rationality of the public speakers is the reality of

disease—and underlying that, the reality of death. Because the speakers are facing this reality themselves or in their loved ones (or, in some cases, in their patients), they use a rhetoric that assumes the legitimacy of *any* option for dealing with the realities of cancer, and more specifically, for the opening of access to options for patients. For example, one patient pleads that “My life, the lives of my family, and women with metastatic breast cancer depend and hang our hope on *anything that can help us to live* and live as fully functioning as the treatment of any metastatic disease will allow (FDA, 2011a, p. 44, emphasis added). The underlying logical claim of this practical legitimizing rhetoric is, “Death is the ultimate reality, and I am facing it. Because death is the other possibility, any and all potential cures, reliefs, and hopes should be open to me, whatever their cost.” In other words, the practical legitimizing rhetoric of the public speakers assumes that decision making in the Avastin case should be based on the fundamental reality that the patients taking Avastin for breast cancer generally have poor prognoses and should therefore be allowed to take any medication they want, whatever its potential effects. This practical rationality finds two main rhetorical expressions in the hearing: statements that claim that *anyone* benefiting is sufficient reason for approval, and statements that claim that *any kind* of benefit counts as a valid outcome for decision-making purposes. These together represent the opposite of calculability in the sense that benefit can be defined in any amount, of any kind—the exact antithesis of Dr. Pazdur’s discussion of the “type and magnitude” of benefit that the FDA would accept.

For example, the phrase “may benefit” is used again and again by the public speakers. One notes that the withdrawal will “halt access for newly-diagnosed women with metastatic cancer who may benefit from this therapy” (p. 20), combining all of the

aspects of a practical legitimizing rhetoric: the reality of cancer, the concomitant assumption that patients facing this reality should have access to any option, and the justifying claim that supports all of it, which is that they *might* benefit. Unlike the bureaucratic speakers, who want to be able to justify their decisions to those who will later occupy their same roles in the bureaucracy as well as to their superiors in the hierarchy, the public speakers do not need any calculable rules for deciding what to try. Because their risk is, essentially, 100%, a risk-benefit ratio is irrelevant and literally uncalculable for them. Any amount of benefit or potential benefit, no matter how small, is a potential improvement when placed into the ratio against a near certainty of dying. Therefore, as opposed to the calculable risk-benefit rules of the bureaucracy, the public uses the pragmatic, practical reasoning that any potential benefit is worth attempting.

This “might benefit” concept occurs again and again, embracing a modality of contingency and possibility, as opposed to the rhetorical determinism of the FDA speakers’ construct of the scientific evidence (Streuver, 2009). One of the public speakers says that “Avastin works for some people” (p. 23). Another says that Avastin was “nor your drug of choice,” but “it was mine” (p. 28). She goes on to say that for “some inexplicable reason, Avastin works successfully in some women such as me” (p. 29), making the underlying pragmatism and what Kalberg calls “egotism” of this legitimizing rhetoric explicit: it does not matter why it works or for how many people, just that it works for some reason for me or those I care about. She later restates this by saying that Avastin is “a treatment for my disease” (p. 30)—not for breast cancer but for *my* disease. Another argues that Avastin can only be prescribed or not “in the context of [the patient’s] individual circumstances” (p. 32), yet another that “each patient is unique”

(p. 35), and a third that Avastin should simply remain available for “those of us who are already seeing its benefits” (p. 40).

A term even arises for the group that does respond to the drug: “super responders” (p. 41). When this term is invoked, the difference between the calculability of bureaucratic rhetoric and the pragmatism of public/patient rhetoric is clear: “Why is Avastin working for me and other super responders?” a woman asks. “I can’t answer that, but it’s working” (p. 41). One doctor who treats cancer patients lists the individual women who have benefited, listing each of their names and their responses to the drug (p. 49). Another doctor argues that “[t]he important question in 2011 is not whether the results of E2100 were true, but rather who benefited from Avastin” (p. 55). (Interestingly, these two doctors and the others who testified as members of the public rather than as FDA speakers indicate that there are multiple views of medicine and that the bureaucratic view of it, which the FDA represents as the *only* view of “clinical meaningfulness,” for example, is very limiting—a contradiction I will discuss in greater length in the conclusion.)

The concept of “those who might benefit” continues to appear throughout the public speakers’ presentations. One survivor argues that “Avastin alone is working for me and thousands of other women,” (p. 56), and another very tellingly pleads for the FDA to “somehow, someway keep Avastin on label” (p. 58), again indicating that rules and procedure are irrelevant in the face of pragmatic, “egotistic” needs of individuals. The husband of one of the survivors supports this idea, noting that the FDA should “leave Avastin available for those it benefits and don’t prescribe it for those it don’t [sic].” He follows with a statement that indicates how clearly he sees this pragmatic view as an

obvious assumption on which to base decisions: “That just makes sense” (p. 62). The point is that it does make sense—it makes *one kind* of sense, in that it is a completely logical and rational approach to health decision making if one acts on the basis of a practical rationality as defined by Kalberg, a rationality based on individuals’ needs and desires as they confront (difficult) realities. Moreover, it is inherently incalculable in being phrased in the subjunctive: people *might* benefit, and that possibility, whether “fact” or not, is sufficient.

The public speakers are even willing to admit that this approach is relatively egotistical in that it benefits a few: Avastin, says one, “does work well for a fortunate minority” (p. 69), and we “may not know in advance for whom Avastin will work and for whom it will fail” (p. 70). The point is that all options should be on the table if there is a chance for even a single individual to benefit. And these speakers go so far as to argue that the calculable-rules-based rationality of the FDA is itself questionable in the face of anyone benefiting, claiming that “the FDA contemptuously ignores these women, dismissively calling them ‘anecdotal evidence’” (p. 88). This is precisely the breakdown between the calculable, formal rationality of the bureaucracy and the practical rationality of the public speakers: what is valid evidence to one simply does not “count” as authoritative to the other. If anyone benefits, the practical realities of living with cancer suggest to the public speakers that they should have access to the drug, while for the FDA, individual benefits are not calculable and therefore not visible as valid evidence. The public speakers are pleading that “my life should be enough” (p. 74), while their individual lives are literally not visible to the calculation instruments by which the FDA’s decisions are made.

Similarly, while the bureaucratic speakers assume that the benefit itself must be of a particular kind—it must be a calculable benefit—the practical rationality of the public speakers is expressed in their ongoing claims that *any kind* of benefit justifies approval, just as benefit to any person or group justifies it. This particularly appears in the public speakers’ descriptions of what they perceive as benefits, almost none of which are calculable (and all of which, as a result, are essentially invisible to the bureaucratic decision-making structure). One survivor, for example, claims that she has gotten to “see my son Adam pitch for his varsity baseball team, to be a partner to my husband, to travel” (p. 41). Another argues that the greatest benefit has been that Avastin has “even given me times when I don’t think about having cancer” (p. 57). One suggests that the real value of a treatment option is its potential to be “the bridge to important life events such as weddings, births, and graduations” (p. 86), while yet another suggests that the drug should be approved if it allows breast cancer patients “one more day with their families” (p. 95). The husband of a patient who died argues that Avastin should be approved because it gave his wife a period of “sports-filled life, virtually doctor-free” (p. 109), essentially arguing that what the bureaucracy perceives as the “gold standard” and the only truly meaningful calculation—survival—is not at all the measure by which patients and other public speakers are determining value. Nor is calculability of survival the basis of their legitimizing rhetoric or their rationality.

It is really this underlying reality that they are all facing—that those patients who receive Avastin for breast cancer are probably going to die anyway because their disease has such a poor prognosis—that drives and underpins all of the assumptions and claims of the practical legitimizing rhetoric of the public speakers. As one speaker puts it, “if I

don't have this drug, I know that I will have death" (p. 101). Or in the words of another, "Everyone I know who has had Stage 4 any kind of cancer has died" (p. 109). As a result, these patients are "willing to deal with greater toxicities than those in earlier treatment stages" (p. 103). These are patients, as one doctor puts it, who are "willing to take greater risks and understand that other treatments have already failed them" (p. 66). These are absolutely pragmatically based decisions, not calculations, about risk. For the patients, their families, and the doctors who participate in the hearing as public speakers, decision making does and should occur on the basis of the practical, individual, "egotistical" concerns ("interests," as Kalberg calls them) of those facing the ultimate realities of disease and death. As one man, the husband of a woman who died of cancer, put it: "Let's face it: it's stage 4 cancer" (p. 120). That concept of "facing" reality, and the assumption that decisions should be made on the basis of having "faced" it, is the underpinning of the practical legitimizing rhetoric.

Substantive Rationality: Access, Choice, and Options

However, the practical reality of facing cancer is not the only driving force behind the public speakers' comments. They also make claims from a values-based or "substantive" rationality. As noted above, Kalberg argued that substantive rationalities are based on "value postulates," or coherent groupings of values or ethical beliefs that hold together to support particular decisions. In the case of the public speakers at the Avastin hearing, the values postulate they express is one that has become popular in recent years as one definition of American democracy: the combination of *individualism* and *choice*. This is particularly of interest here because it suggests even more strongly that the conflating of bureaucracy and "governing" at the agency level with politics and

political rhetoric hides a rather substantial philosophical difference between the two—a philosophical difference that is at the heart of the public’s increasing distrust for what they perceive as antidemocratic decision-making processes in agencies such as the FDA.

On the other hand, the discourse of democracy taken up by the public speakers is not without its own problems. The form of political organization known as democracy is itself complex and widely varied in both its definitions and its applications, from parliamentary democracies to socialist ones, each employing the basic premise that “the people” should drive the forms and functions of governance. The discourse of choice and individualism adopted by the public speakers in the Avastin hearing is just one—and a relatively recent—concept of democracy, one driven more by consumerism and capitalism than by democratic ideals *per se*. It is this capitalist, consumerist ideology of democracy as freedom of individual choice that makes Genentech such a strong advocate of the inclusion of the public speakers in the hearing; the equation of “choice” and “individualism” with democratic ideals is far more convincing coming from the public than from Genentech, and their strong advocacy of it allows Genentech to hitch its own claims to a democratic appeal without having to make that appeal itself (which is not in line with its need to speak to the FDA in the agency’s own language).

This is not to say that the public speakers are either disingenuous or even consumerist; what can be said with certainty about the public speakers at this hearing is that they are, and perceived themselves to be, in dire straits. They have been given death sentences. It is no wonder that they adopt whatever powerful discourse is available to them to support their claim to continue taking Avastin. Indeed, although expressed in terms of individualism and choice, their rhetoric (as I discussed in Chapter 2) is one of

risk acceptance and uncertainty acceptance. Unlike the FDA, which wants, or needs, to reduce complexity and uncertainty to justify a decision, the public speakers embrace uncertainty and irreducible complexity because certainty, for them, is death. The discourses of individualism and choice are readily available to them, already powerful in the American consciousness, as a way to talk about the very limited choice available to them and the acceptance of risk that limitation promotes¹³.

The individualism of the public speakers has already been discussed; it is expressed in their claims that individual lives, individually defined types and amounts of benefit, and individual beliefs about whether to take a drug or not should govern the decision-making process. The other half of their values postulate is the concept of choice. Again and again, the public speakers argue not only that individual choice should be the basis of decision making, but that this is an *ethical* consideration and one that is or should be typical of the United States—that is, a (or one concept of a) democracy—specifically.

References to the idea that choice should be the ultimate goal in this and other public health decisions occur frequently during the public speakers' presentations. They ask the FDA “not to limit the treatment options” (p. 22). They equate this choice with “freedom” and argue that it would be “ethically wrong” to take away this choice (p. 35).

¹³ One thing that is potentially interesting about the public speakers' use of this discourse—interesting, at least, for the study of discourses of democracy—is that the public speakers cling to the promise of choice in the face of the loss of all *meaningful* action. They have been given essentially inevitable death sentences; there is little or nothing they can actually do about their disease except choose which medicine to take (buy). There is a possible connection here to the consumerist discourse of democracy that has gained popularity in the past 20 years or so in the U.S.; perhaps Americans are likewise clinging to and insisting upon their right to choose products in the absence of any ability to make *real* change or engage in *meaningful* intervention in government. This is not a connection I address here but one that would reward further study.

They indicate that the choice is ethical because it is two-sided, applying to both those who want it and those who do not: “Don’t prescribe it, don’t use it, but don’t take it away from me” (p. 37). They argue that the real value is not in the drug’s benefits but merely its availability *as* a choice: “I am pleading with you today to keep my miracle drug Avastin available for all breast cancer patients” (p. 40). Some beg the FDA “not to limit access” (p. 48), while others accuse that it is “simply wrong” to hold the drug to a calculable rule rather than allowing doctors to “select patients for Avastin use” themselves (p. 64). One of the doctors claims that it is the patients who should and can “decide what treatment options are best for them” (p. 65) and that they “deserve the choice” (p. 66). In his allotted 3 minutes, this doctor uses the words “choice,” “access,” and “preferences” twice each, and the word “options” four times (pp. 65-68). An advocate for a cancer patients’ organization claims that cancer patients should be allowed to take on any “side effects and risks they choose to assume” (p. 78), and another outright accuses the FDA of opposing “justice and common sense” if they deprive women of the opportunity to make “this life-and-death decision” themselves or with their doctors (p. 89). The examples continue throughout the public presentation, all demonstrating the same underlying assumption: that decision making in health is a matter of choice, and that allowing patients that choice is not merely one possibility but the correct *ethical* approach, given a particular set of values.

That the public speakers see that set of values as explicitly democratic is clear not only from the fact that the values postulate of individualism and choice is a commonly expressed values postulate of modern American democracy, but also from explicit statements made during the presentation. For example, one cancer patient advocate

compares the United States' regulatory decisions to those in other Western democracies, particularly those of Western Europe, expressing deep disbelief that the United States—implied here as the country that *should* be most reflective of democratic practice—is falling behind. She refers to a study that found that, compared to Europeans, “millions of Americans do not have access to the latest, most innovative medical care,” then draws the conclusion that the American regulatory process is itself to blame and should be changed so that “Americans have access” to the latest drugs—thus directly relating the concepts of choice and access with what she believes *should* characterize American democratic government (p. 77). Even more explicit is the statement by a breast cancer patient: “I never thought [patients] in the United States would have to beg for a drug that is keeping me and others alive” (p. 29). The clear implication here is that the United States is supposed to be special, that it should be held to a higher standard, and that that standard is specifically marked by *access*. The substantive rhetoric of the public speakers is based explicitly on the values postulate of American democracy (or rather, one concept of the values postulate of American democracy): the combination of individualism and choice.

Taken together, the practical (“egotistical” and “interest-based,” in Kalberg’s terms) and the substantive (“ethical” or “values-based”) legitimizing rhetoric of the public speakers is perfectly summed up in a phrase used by one of those speakers, a representative for a patient organization who pleads for Avastin not to be “withheld from all patients because not everyone benefits equally” (p. 79). The phrase she uses to describe public health ties together both the pragmatic, reality-facing rhetoric of practical rationality and the values-expressive rhetoric of substantive rationality: public health, to her, is “an ethical practice” (p. 79). That phrase—*ethical practice*—sums up the

assumptions about health and health decision making that underlie all of the public speakers' statements, which in turn make up their legitimizing rhetoric. The fundamental disconnect between the vision of medicine implied by a rhetoric of *ethical practice* and the vision implied by a rhetoric of *bureaucratic procedure* will be one of the focal issues addressed in the conclusion.

Conclusion: Dominance Legitimized by [a] Rationality

Weber described bureaucracy as dominance legitimized by rationality—as opposed to, for example, the kinds of dominance legitimized by tradition or by strong personalities. Kalberg, however—in tacit agreement with many scholars in rhetoric, as well as those in philosophy and sociology—argued that rather than “rationality,” we should speak of multiple rationalities, systems of justification on which to base decisions, all of which are equally internally consistent but which are based on very different fundamental principles. Following Kalberg, then, it makes sense to rephrase Weber to argue that bureaucracy is dominance legitimized by *a* rationality—the calculable, rule-based rationality Kalberg described as “formal.” Unfortunately, the FDA hearing suggests that the formal rationality of the bureaucracy is at odds with the rationality of the public speakers (members of the very citizenry the FDA is supposed to be serving), who base their assumptions about how to make public health decisions on a practical-substantive rationality, a combination of pragmatic “egotistical” reactions to the realities of death and ethical claims about individualism and choice.

In any decision-making situation, competing rationalities—expressed through the competing legitimizing rhetorics of the various stakeholders—make coming to consensus difficult. However, the next chapter will show that the structure of the hearing is such

that the public speakers are *not* full participants in the discussion; the competing rationalities and legitimizing rhetorics never actually interact at all. Rather, the dominance of the bureaucratic decision-making method and the particular rationality by which it is legitimized are supported by the structure of the hearing such that “the record” reflects only the bureaucracy’s decisions and rationality as valid. In fact, although I will focus on the rhetorical use of reformulations to ensure the success of the bureaucracy in the next chapter, it is also worth noting here that the reformulations are only necessary *for* the bureaucracy itself and its own record, not to oppose or critique the public’s statements. Those statements, and the particular practical-substantive legitimizing rhetoric of the public speakers more generally, are never explicitly opposed by the FDA speakers; they are simply ignored. In fact, perhaps the most telling—and galling—aspect of the structure of the hearing itself, in terms of explaining how the public speakers’ rationality is simply ignored, is what the public speakers are called. They get to speak first, but this is no mark of regard. Rather, it is to get out of the way early those speakers whose opinion was never intended to count—or as the transcript refers to them, the “Nonparties.”

CHAPTER 4

AUDIENCE ANALYSIS

It is hard not to feel, as one reads the transcript, that the decision about Avastin has already been made, that the specific decision about the withdrawal of the breast cancer indication of this drug is not in fact the point at issue, and that the specific audience gathered in the room—the patients, families, and doctors actually affected by the decision—are not the audience actually being addressed. As was discussed in the previous chapter, several of the CDER presenters in fact make it clear that the Avastin decision *has* already been made—months earlier, in the official meeting of ODAC, long before this hearing was conceived. “Following a careful review and discussion of the available data,” as Dr. Pazdur put it near the opening of his presentation, “the members of the committee recommended nearly unanimously, 12 to 1, that the indication for breast cancer be withdrawn” (FDA, 2011a, p. 136). Again and again, the FDA speakers refer to previous decisions as if they were final or conclusive, with Dr. Pai-Scherf, for example, mentioning the unanimity or near-unanimity of ODAC’s decisions about Avastin three times in one paragraph (p. 162).

These references to the previous votes of the ODAC committee members are not lost on the public speakers or Genentech, who are well aware that the committee making the decision at the current hearing is, in all but one of its voting members, exactly the same committee that made the previous decisions against Avastin. One of Genentech’s

lawyers, Michael Labson, in fact petitioned the FDA to seat a new ODAC panel for the hearing, noting that the current members had not only already demonstrated their feelings and beliefs about Avastin by voting against it multiple times, but had spoken to the press, defending their decisions and providing public rationales for them—actions that gave them far too much interest in maintaining the consistency of those very publicly-stated views, in his opinion, and made them potentially biased in the new hearing (Silverman, 2011).

The popular press was also aware, ahead of the hearing, of the very low potential for the hearing to affect the ruling on Avastin. As the *New York Times* reported:

The F.D.A.’s cancer drug advisory committee voted 12 to 1 last July that the approval for the treatment of breast cancer be revoked. The hearing this week will be before the same committee, which will make recommendations to the F.D.A. commissioner. Of the six voting members expected to attend, five voted to revoke the approval last July. The sixth was not at that earlier meeting. Since the data have not changed, Genentech, in the summary of its arguments, concedes it is not likely to change the committee’s mind about the benefits of Avastin. (Pollack, 2011, n.p.)

Similarly, the *Wall Street Journal*, in characteristic fashion, ran an editorial titled “The Avastin Mugging: The FDA Rigs the Verdict Against a Good Cancer Drug” (2010), in which it explicitly accused the agency of having already made up its mind against the drug for a host of reasons¹⁴.

Patients and patient organizations were aware of the apparent pre-disposition of the committee as well. An article on the advocacy site *Freedom of Access to Medicines*

¹⁴ As it its wont, the *Wall Street Journal* places heavy emphasis on cost, arguing that the FDA had made up its mind not to approve Avastin because of the (claimed) \$88,000-a-year price tag, but the editorial also argues that the hearing demonstrates that “the FDA’s regulatory afflatus is more important than options for actual patients” and that “[w]hile ODAC is ostensibly independent, it is in practice a creature of the FDA” (*WSJ* Aug. 18, 2010, online), an issue I address more fully later in this chapter.

provided an overview of the run-up to the hearing, offering detailed commentary about the FDA's initial—and rather stringent—opposition to allowing the public to speak at the hearing at all. CDER's argument for keeping patients and other public advocates out of the hearing was that there had already been "'ample opportunity' for input" (Sutter, 2011). Perhaps the statement most indicative of a predetermined decision—a decision that actively excluded even an *intent* to speak or listen to the public during the hearing—came from one of the members of ODAC during one of his final speeches. In defending his "no" vote in response to one of the key questions of the hearing, Dr. Ralph Freeman said, "I have to say that I struggled with this and struggled with this until just before the meeting" (FDA, 2011b, p. 266). In other words, he struggled with the data—the data that even the *New York Times* identified as exactly the same data presented to Dr. Freeman and the other members of ODAC when they made the same decision previously—up until the moment *just before* the presenters at the hearing started speaking, at which point his mind was already made up.

Clearly, this is a committee that has not only come into the hearing predetermined on a single outcome, but also one that has no qualms about making that predetermination apparent to those present. This suggests quite strongly that those present in the room, in addition to being not the real parties to the issue at hand, are also not the actual audience of the hearing. The public was not, in the FDA's opinion, even supposed to be in the room; only because of constant pressure from advocacy groups and Genentech were the public speakers even allowed the 3 minutes apiece they were finally granted. So if the people and groups actually in the room at the time of the hearing were not, in fact, the audience of the hearing, then who is the real audience here? Or, in the case of the

bureaucracy, *what* is the audience? I will argue that for any bureaucratic speaker—and for the ODAC speakers who represent the final voice of the FDA and its decision in the Avastin hearing—the audience being addressed is always the record and thus indirectly the bureaucracy itself.

I will argue this through the demonstration of three subclaims. First, I will show that the ODAC speakers use reformulations to achieve Fact-Like Status (FLS) for their own claims, regardless of whether anyone in the room is convinced that FLS has been achieved or whether those claims are correct. Second, I will point to a collusion between the supposedly separate “insider” and “outsider” committees (the official FDA committee, which is CDER, and the panel of supposed outsiders whose job is to “formulate recommendations” to the FDA, which is ODAC) that demonstrates that the two are working together to reify and achieve FLS for a broadly bureaucratic public health agenda. Third, I will demonstrate that the structure of the hearing itself, which is determined by the FDA, is organized precisely such that the FLS-achieving statements of ODAC are the very last ones made and therefore stand as the final word in the official record of the hearing, the transcript. Taken together, these maneuvers, both the explicitly rhetorical maneuvers and the structural ones that support them, suggest very powerfully that the FDA speakers are primarily concerned with the bureaucratic record itself as both audience and expression of power—and that the members of the public are truly, as the record says, nonparties to the event.

Reformulations and Fact-Like Status

In *Laboratory Life*, Bruno Latour and Steve Woolgar described the making—the bringing-into-being—of scientific “facts,” which they defined as those beliefs, ideas, or

objects that are “taken-for-granted” by the members of a scientific or expert community (p. 76). Critically, Latour and Woolgar (1979) defined the bringing-into-being of such “facts” not as a series of laboratory experiments or scientific discoveries, but as a series of statements. Fact-making, the transformation of an idea or concept into a taken-for-granted item of knowledge, was therefore highly or even purely rhetorical. Latour and Woolgar outlined five stages of “fact,” in which modalities—“statements about other statements” (p. 77) that made the original statements appear supported or refuted, or whole or limited—were stripped from the knowledge item, leaving it to stand on its own as if unproduced, simply there in the world. These pieces of knowledge were in fact highly dependent on the circumstances of their production, they argued, but the stages of removal of modalities made them appear less and less dependent on those circumstances and more and more universally, unquestionably true.

Latour (1987) provides a helpful graphical illustration of this concept in the later *Science in Action*, in which he incorporates a number of statements, along with drawings of humans and technological machines of production, into a sequence. The cartoon depicts both the adding-on of modalities (making a statement less like a fact) and their removal (making the statement appear more factual). The second half of the cartoon, in which the removal of modalities is depicted, moves in the following fashion. First, a group of people (these could be scientists but need not be) discuss the possible shape of the DNA molecule. “Maybe it is a triple helix,” says one. “It is not a helix at all,” says another. At the end of the panel, two figures together (presumably Watson and Crick, but not necessarily), say “If it had the shape of a double helix.” Notice here that there is no consensus, no fact as yet, only a group of people debating possibilities. Even the final

two people in the panel maintain a very strong modality in the word *if*. In the next panel, two people discuss that “if,” noting that “This would explain Chargaff” and saying “and it would be pretty,” two statements that are themselves modalities for the statement “the DNA is a double helix,” since they provide reasons to believe or supports for that statement. Such modalities *remind* a hearer that a statement is a hypothetical, a construct of the human mind, and dependent on its productive and intellectual circumstances for its (apparent) validity.

In the next panel, the modalities are stronger in favor of the double helix statement. A group of four people all speak in the same speech bubble, representing a building consensus. “They say that Watson and Crick have shown that the DNA is a double helix,” this group reports. The modalities are still very clear despite the increase in both agreement about and strength of statement regarding the aspiring “fact.” The phrase “they say” reminds the hearer that the statement *is* only a statement, while the reference to Watson and Crick very clearly places the concept of the double helix into the circumstances of its production—the laboratory of Watson and Crick, two humans forming hypotheses about the world. In the following panel, though, humans have disappeared, and the “speaker” is a book, presumably a scientific work. Here, a speech bubble includes a phrase that is in quotation marks in the cartoon: ““Watson and Crick have shown that the DNA molecule has the shape of the double helix.”” The human speakers have gone, leaving the appearance of a more authoritative statement, but the reference to the production of the statement—“Watson and Crick have shown”—remains, and the quotation marks around the statement also indicate that it is taken *from* human speech, if not related in that medium. However, in the final panel, no book appears, and

no human. There is no speaker at all, just a statement, *without* quotation marks this time: “Since the molecule of DNA has the shape of a double helix the replication of genes is made understandable.” In this panel, all graphical (quotation marks), speaker (human or book), and linguistic (references to labs or speakers) indications of the circumstances of production have been eliminated. The statement stands alone, as if unproduced and simply “there.” Moreover, it is used as a presupposition in a “since” phrase, increasing the sense that this statement—“the molecule of DNA has the shape of a double helix”—was never produced in a laboratory as the result of debate in response to various constraints and decisions but is merely “there,” universally true such that other statements can be built on it (p. 14). The statement has achieved the status of fact, or as Latour and Woolgar put it, Fact-Like Status (FLS), or facticity.

What is perhaps most interesting and important about statements that have achieved FLS is what Latour and Woolgar said about them in *Laboratory Life*: “Precisely because they were taken for granted, our observer found that such statements rarely featured in discussions between laboratory members, except when newcomers to the laboratory required some introduction to them” (p. 76). At one “extreme,” he noted, “readers are so persuaded of the existence of facts that no explicit reference is made to them,” and they became “tacit knowledge” (p. 76). It is key that such statements are rarely discussed among experts and only come under scrutiny when *newcomers* to the lab ask about them. In the Avastin hearing, one of the effects of the achievement of FLS by the FDA for their own understanding of the correct decision-making processes and measures is to effectively transform the public into “newcomers”—those who “don’t understand” the obvious facts that are clear to all the “experts.”

In the Avastin hearing, because all statements, procedures, and beliefs are (at least nominally) available for debate—specifically because the hearing *is* supposed to be a debate—no statements are automatically accorded FLS. Rather, the hearing itself becomes a factory for the production of FLS, or perhaps more accurately, a sparring gym in which each contestant fights to achieve FLS for his or her own “side” and to undermine FLS for (to introduce uncertainty into) the statements made by their opponents. The transcript thus becomes an ever-lengthening sheet onto which statements are being printed, with each statement according more or less FLS to a particular idea in an attempt to either open up earlier statements to doubt or cement earlier statements into facticity. Because they are the only speakers who are given the right to vote on the issues and express their opinions about those votes, and because they can ask as many questions as they want of any participant without having to answer any, the members of the ODAC panel are both in the best position to achieve FLS for their own beliefs and statements and the most likely to achieve uncertainty (undermine FLS) for the statements of their opponents.

However, it is also important to note that all of the parties are coming into the hearing well aware, as was noted above, that the ODAC committee had already achieved FLS for all of these concepts in their own minds, and that they intended to essentially re-achieve, or publicly achieve, that same FLS in the hearing. It is ironic that the result of this is that the private corporation, Genentech, wanted the public to be present at the hearing because they were well aware that the public’s argument would support their own and that public pressure was the only way that a Genentech-favorable opinion could even possibly be reached (although this was always unlikely). Because Genentech absolutely

relies on the FDA for approval for all of its products, its own rhetoric in the hearing is nearly identical to the FDA's (although in favor of approval); Genentech needs the public to make an argument Genentech cannot. Meanwhile, the FDA—the agency intended to work for the public good—tried very hard to keep the public from even attending the hearing in the first place, for the same reason. The public acts like “newcomers to the lab,” people to whom the understood, assumed definitions and procedures must be explained, providing an opportunity for Genentech because once the public is present, those assumptions must be re-opened and FLS for them re-achieved¹⁵.

Since Latour and Woolgar defined facticity as explicitly rhetorical, it is not surprising that rhetorical tactics are used by the various groups, and especially by the ODAC speakers, to achieve that facticity. In particular, they use reformulations to do so. As was discussed in Chapter 2, reformulation refers to the apparently simple action of “mak[ing] the same point in different words” (Levinson, 1983). This simple action, however, can have powerful consequences if the statement *appears* to make “the same point” but in fact either increases or decreases the modalities, and thus the facticity, of the statement. Teachers use this method very often. For example, if a student answers a question by saying that “The way to proofread a paper is by reading it backward, one line at a time,” the teacher might reformulate the statement by saying, “Yes, one way to

¹⁵ There is, of course, also an element of “political theater” to this. While the presence of the public does mean that claims that could otherwise simply be assumed (for example, that “quality of life” can only be counted in an FDA decision if it is presented in calculable terms, not in subjective, individual measurements) are re-opened to debate and must re-achieve FLS, nonetheless, it is still true that the parties to the hearing admitted ahead of time that it was beyond unlikely that the ODAC members would vote differently in this case, public speakers or no public speakers. This “theater” aspect relates very closely to the concept of “fake participation,” a growing concern for many political and bureaucratic entities that I will explore in more detail in the conclusion.

proofread a paper is by reading backward.” The statements are nearly identical but not quite—and it is that “not quite” that makes the difference. The student’s statement very strongly argues for its own facticity (“*the* way . . .”), while the teacher’s reformulation opens the statement to other options (“*one* way . . .”). Teachers also use reformulations in the other direction, to increase FLS for statements they wish to build from. Imagine a student who answers a question by saying, “Maybe it was in 1918?” If the teacher wants to accord that statement factual status in order to encourage other students to build from it, she might say, “Okay, so since it was in 1918, what else was going on at that time in history?” Using the phrase again but reformulating it without the “maybe,” and using it as a presupposition (which specifically marks it as “taken-for-granted”) the reformulator achieves a measure of FLS for this statement that allows other students to take it as fact and build upon it.

The ODAC speakers use the same kinds of strengthening and weakening reformulations in the final portion of the hearing—the time during which they are allowed to ask questions of the other participants before then voting on each of the proposals set for the hearing and finally providing their rationales for voting as they did. In this context, a strengthening reformulation will mean one in which the speaker appears to reiterate a previous statement but in fact accords it increased FLS, while a weakening reformulation will mean one in which the speaker appears to reiterate a previous statement but in fact opens it further to doubt and decreases its proximity to FLS.

For example, in describing the benefit Avastin has been shown to provide, three ODAC speakers build upon and reformulate one another’s statements to create, in the last speaker’s statements, a claim with very high FLS that Avastin has no benefit. Dr. Logan

speaks first, noting that “the modest magnitude of benefit in progression-free-survival that we have seen in the combined data is not substantial enough to justify this additional toxicity” (FDA, 2011b, p. 245). This statement does include modalities pointing to the circumstances of its production, particularly the phrase, “that we have seen in the combined data.” This phrase reminds the hearer that his statement is not fact but a reference to a set of numbers, as well as his (and others’) interpretation of those numbers. However, his statement also embeds the idea of a “modest magnitude of benefit” in the sentence as a presupposed item of knowledge. While in fact whether or not the amount of benefit *was* modest is precisely one of the points at issue, Dr. Logan presents it as a given, a basis upon which to compare risks. Combining the presupposition with the modalities makes this a statement that is certainly approaching FLS for the idea that Avastin offers no worthwhile or acceptable level of benefit, but that claim is still uncertain.

The next speaker reformulates the same idea, noting that “The evidence that was presented to us demonstrates that there is a high risk to patients with little or no demonstrated clinical benefit” (p. 246). Here again, the speaker assigns modalities to her statement (“the evidence,” “demonstrates”), but she also reformulates Dr. Logan’s statement about “modest magnitude of benefit in progression-free survival” to the much stronger “little or no demonstrated clinical benefit.” Together, despite maintaining modalities referring to the reasons for believing the statements, these two speakers have moved a step closer to facticity for the claim that Avastin has no worthwhile or acceptable benefits.

The next speaker accomplishes the final move to facticity by removing all modalities *and* embedding the statement as a presupposition. He makes the same—or apparently the same—comparison between low benefit and high risk, but his phrasing is much different. “[I]n the absence of clinical benefit,” he says, “I do not believe any toxicity is acceptable” (p. 247). Here, the three speakers have moved from “modest magnitude” of benefit to “little or no demonstrated clinical benefit” to “absence of clinical benefit,” the strong final statement that stands as the last word in the record on this question. Moreover, the statement has moved from a claim embedded in the circumstances of its production through references to the data and the hearing itself to a claim that stands alone, without reference to speakers or production: “*the* absence of clinical benefit.” This is now, as it stands, presented as taken-for-granted expert knowledge. This reformulation sequence is rhetorically interesting in part because it moves in gradual steps—in *precisely* the gradual steps outlined by Latour and Woolgar as the stages between uncertain knowledge and facticity—from a statement of a relatively well-agreed-upon interpretation of the data that other parties in the hearing might agree with and had in fact stated (that the benefits could be described as “modest”) to a statement only in line with the FDA’s predetermined outcome and desired claim (that *no* benefit exists). Thus, the reformulation allows the speakers, in succession, to move toward facticity, removing modalities one at a time, so that the FDA’s move to achieve FLS for its own predetermined ideas is very subtle and hardly visible, yet the strongest possible statement of the claim is achieved at the end.

The ODAC speakers go through this process many times during their portion of the hearing. However, an extended example occurs near the very end of the hearing that

captures the process over the course of an exchange between the ODAC speakers and the Genentech representatives, who respond to the ODAC members but are not allowed to ask questions themselves. Examining this exchange in detail will demonstrate the ways that both sides attempt to achieve FLS for their own claims and approaches and to undo FLS for—to introduce uncertainty into—the claims and approaches of their opponents. It will particularly show the ways in which the ODAC speakers work together to finish the sequence with a strong, unequivocal statement of their own belief as the final statement on this topic in the hearing, suggesting that it is indeed the FLS achieved in the record, and not the persuasion of any of those actually present in the hearing, that is the purpose of the ODAC speakers’ statements—that the record, in other words, is the “audience” of the hearing, standing in for later bureaucratic speakers who will use that record to legitimize their own actions.

The exchange (see Appendix for complete excerpt—all emphasis in the Appendix and in excerpts below is mine) begins as a discussion of endpoints and outcomes:

DR. BALIS: We talked a little bit about quality of life, since I think we’re going to have difficulty with overall survival as a potential endpoint. One of the points that was made as a secondary endpoint was that the drug produced more objective responses than the chemotherapy alone.
From Dr. O’Shaughnessy’s talk, I gather that most of these patients who are treated with the drug are symptomatic at the time they get it. And the question I have for her is, **is response a surrogate for relief of symptoms in these patients?** (p. 231)

Dr. Balis, one of the ODAC members, notes that Genentech has claimed “objective response rate”—that is, the number of patients with a reduction in tumor size—as one of the alternative endpoints that should be examined. If the ODAC committee is to achieve FLS for its decision, and especially for the claim that the benefits of the drug not only do not outweigh the risks but that there is a total “absence of clinical benefit,” the committee

members must destroy the notion that “objective response rate,” which did improve with Avastin, counts as a valid endpoint. Dr. Balis begins by asking what appears to be a very simple question: “is response a surrogate for relief of symptoms in these patients?” In other words, he is asking whether the objective response—the reduction of tumor size—meant fewer symptoms such as pain for patients. This is very important for Genentech to demonstrate because if reduced tumors mean improved quality of life or other such benefits, then Avastin does have benefits even if survival or progression-free survival do not improve. This is, in fact, what the public has been arguing, so it is key for the achievement of FLS around the idea that there are no real benefits that the ODAC committee break any connection between increases in objective response rate and improvements in quality of life (or, as Dr. Balis has put it here, “reduction in symptoms”).

Dr. O’Shaunnessy, one of the Genentech representatives, responds to Dr. Balis’s question:

DR. O’SHAUGHNESSY: Yes. Response rate can be helpful for two groups of patients, one, those who are already symptomatic; there’s no question. The higher the response rate, the higher the percentage of patients who will get clinical benefit, relief of symptoms.

The other group are people who if they do not get a response, that within a relatively short period of time, they will have significant symptoms, or threatening end organ functions. A response for those patients as well, I believe, translates into clinical benefit.

So I think those are the two places, so that doesn’t mean everybody, but it means those particular patients with usually symptomatic, more rapidly advancing disease. (pp. 231-232)

In other words, patients who are already experiencing symptoms will see a reduction in those symptoms, while those who are not yet symptomatic will go longer without seeing them. This is not only a very strong statement—an attempt at FLS for her own

position—but an attempt to connect objective response rate not with the concept of quality of life but with the FDA’s own stated endpoint: clinical benefit.

It is critical, then, that the next ODAC speaker (Dr. Sekeres) specifically returns to the attempt to correlate objective response rate not with clinical benefit (previously the central focus of all the FDA speakers’ claims) but with quality of life:

DR. SEKERES: Can I ask a follow-up question, Dr. O’Shaughnessy? **So did response correlate with an improvement in the FACT-B scores in those patients?** (p. 232)

This is a particularly interesting move given that the FDA speakers have, throughout the hearing, stayed clear of the quality of life issue precisely because the definition—and the meaning to individuals—of a concept like quality of life can be quite ambiguous and personal, but here the ODAC speakers specifically return to the concept repeatedly. Moreover, this speaker actually appears to strengthen the statement of correlation between objective response rate and quality of life. “So did response,” Dr. Sekeres asks, “correlate with an improvement in the FACT-B scores in those patients?”

This statement reveals both of the pieces of the reformulation that the ODAC speakers are attempting. The first is a move toward FLS for a particular concept of quality of life, a measurable, calculable concept of quality of life embodied in the FACT-B, a questionnaire used by many clinical trials to attempt to quantify quality of life—and an instrument that, in addition to the inherent problems of self-report questionnaires generally, is widely disliked by patients’ groups who do not want quality of life to become a quantifiable concept. The second part of the reformulation is dependent on the first: if the ODAC speakers can achieve FLS for the claim that quality of life is

synonymous with FACT-B scores, then they can also achieve FLS for the claim that objective response rate does not correlate with quality of life “benefits” to patients.

Notice, then, how Dr. Reimann (of Genentech) responds, not by strengthening the earlier claim to clinical benefit, but instead specifically responding to the FLS attempt by introducing uncertainty into the claim—which is only barely implied at this point—that the FACT-B is synonymous with improved quality of life:

DR. REIMANN: As you know, **response can happen at different time points on the study, and the FACT-B instrument was collected also at different time points of the study. So we don’t have a correlation between changes in FACT-B score.** We did look, but we didn’t see a correlation, but it is a bit challenging, based on the timing of the FACT-B and the timing of the tumor assessments. (p. 232)

Before even answering the question, he prefaces his answer by saying, “As you know, response can happen at different times points in the study, and the FACT-B instrument was collected also at different time points of the study.” These statements exactly mirror Latour’s claims about the use of modalities; while Dr. Sekeres used a statement that presumed that the FACT-B was a valid instrument and separated it from the circumstances of its production and use, Dr. Reimann intentionally introduces modalities that point to the FACT-B not as a “fact” but as an *instrument*, used *by* people, in particular circumstances. After introducing these modalities as a counter to the attempt at facticity for the FACT-B instrument, Dr. Reimann then directly answers the question: “So we don’t have a correlation between changes in FACT-B score [*sic*].” Even here, though, in his direct “no” answer to Dr. Sekeres, he is introducing modalities into the apparent facticity of the FACT-B, referring not to FACT-B alone but to “FACT-B scores,” reminding hearers again that this is a human instrument, but more importantly saying “we don’t have a correlation” rather than “there is no correlation.” Dr. Sekeres’

statement removed all references to the ways in which the FACT-B is a (fallible) instrument used by people in particular circumstances with more or less validity. Saying “we don’t have a correlation” reinserts those realities by placing the FACT-B in the context of human use and implying that a correlation could exist even if one has not yet been seen in these particular studies.

Dr. Sekeres responds by again attempting to remove the modalities that make the FACT-B a fallible instrument:

DR. SEKERES: Though, presumably, people who were responding at one time point would be responding to when the next FACT-B would be administered to those patients? (pp. 232-233)

Although he does include a statement about the FACT-B being administered, meaning it is an instrument used by humans, he more importantly manages to achieve facticity for that instrument through the implication in this sentence that “people who were responding” is synonymous with the FACT-B scores. He never refers, in fact, to FACT-B *scores* here at all; instead, he simply refers to “people who were responding,” implying that “responding”—that is, experiencing an improved quality of life—would *have* to be reported in the FACT-B because increased quality of life is synonymous with FACT-B scores.

Dr. Reimann, another of the Genentech representatives, takes over here from Dr. O’Shaughnessy and makes another attempt to introduce uncertainty into the presumed FLS of the synonymy of the FACT-B instrument with quality of life:

DR. REIMANN: We don’t have a correlation of FACT-B changes and objective response rate in AVADO. (p. 233)

This statement introduces three key modalities. First, Dr. Reimann repeats the phrase “we don’t have,” implying that such a correlation could still exist even if not measured in

the particular circumstances of this clinical trial. Second, he implicitly reminds the ODAC speakers that the correlation in question is in fact not between FACT-B and quality of life, but between FACT-B and objective response rate—that the two calculable measurements can be correlated but that quality of life is a more abstract and personal concept. Finally, he introduces the phrase “in AVADO.” AVADO is one of the clinical trials. It happens to be the one about which he has been asked, and since he has to answer specific questions, he must use AVADO to answer the question, but here he introduces another modality by reminding the ODAC panel that this is one result, from one study out of a group of studies. It is not a *fact* that could be stated, “the FACT-B scores show that there is no quality of life improvement,” which is the claim for which ODAC is attempting to achieve facticity. (It is interesting, given that this claim has not been explicitly made, that the Genentech speakers are responding so uniformly *to* that implied claim; this suggests that the ODAC committee members’ attempts at FLS status for that claim are clear to the Genentech speakers and not just artifacts of the transcript or the analysis.)

Dr. Sekeres of the ODAC committee responds in the way that is typical of the ODAC speakers in this exchange: he acts as if the Genentech representative had not spoken at all, continuing instead to build on the strength of his own previous statement and the other ODAC speakers’ statements toward facticity:

DR. SEKERES: So there is no correlation between a validated instrument measuring quality of life and response to Avastin? (p. 233)

Three things are important here. The first is the “so” and the implication that he is simply restating, or putting “in other words,” what the Genentech representative said. However, he is not simply stating the same thing in other words; he is rephrasing—reformulating—

the claim so that it matches his own belief about FACT-B, not the original speaker's.

The second important move here is Dr. Sekeres' stepping up of the strength of the claim about FACT-B, again by appearing to simply rephrase the same concept. Here he says, "a validated instrument measuring quality of life" rather than "FACT-B." This not only presupposes that FACT-B is actually a validated instrument measuring quality of life, but more importantly implies that because there is no correlation between FACT-B and response rate, there is no correlation between response rate and "any valid measure" of quality of life—implying simultaneously that there is no quality of life improvement and that any measure (such as the public's) that suggests there was quality of life improvement was not valid.

Finally, the third thing accomplished here is that Dr. Sekeres reformulates "objective response rate" into "response to Avastin." While the two may appear to be synonymous, and while he could claim that they were synonymous if appealed to, in fact the phrase "response to Avastin" suggests a much larger claim. As stated, his phrasing implies that there is no correlation between a valid quality of life instrument and *any* type of response to Avastin. This is a great deal to accomplish in a single short sentence, and it is all accomplished by reformulating what has been said by the Genentech speakers—that is, by appearing to simply restate the same concept (introduced by the "so" that seems to imply that it is just a simple restatement) while in fact changing the phrasings of each of the terms in subtle but important ways that help achieve facticity for his own claims.

Dr. Reimann responds in an even stronger attempt to interject uncertainty about the FACT-B—an attempt, in other words, to reintroduce modalities and reduce the fast-

increasing FLS of the claim that the lack of correlation between FACT-B and objective response rate in this study indicates that no quality of life improvements exist with

Avastin at all:

DR. REIMANN: It is a valid instrument in assessing quality of life. I think the question is, **is it sensitive in this patient population?** In a front-line setting, in a typical front-line population, probably fewer than 20 percent of patients are symptomatic. And that's the studies that are done by any sponsors. They have a mixture of ECOG zero and 1 patients. So I think **you'd really want to focus on symptomatic patients, and that's a smaller group.** (p. 233)

Again, he reintroduces the concept of the FACT-B as a potentially fallible instrument (whether “valid” or not) with its own limitations, which may be coming into play in a particular setting in which that instrument is used—the precise kinds of modal statements about the circumstances of production that Latour argued reduce FLS.

Yet again, though, Dr. Sekeres responds as if the Genentech representative has not even spoken, simply building on his own previous statement and yet again introducing his claim with the “so” that suggests a restatement of what has just been said:

DR. SEKERES: **So I think probably, the best instrument out there for measuring quality of life, in the U.S. at least, is the FACT for a number of different cancers, including breast cancer. And we don't have a clear correlation between improvement in a woman's well-being, how she reports it herself and response to a drug.** (pp. 233-234)

Again, he increases the strength of the claim about the FACT-B (“the best instrument out there for measuring quality of life”). Again, he replaces measured scores on a particular instrument with a phrase with much broader application and stronger meaning (“a woman's well-being, how she reports it”). And perhaps more problematically here, he conflates “how she reports it herself” with the FACT-B, totally eliding the entire several-hour presentation in which women *did* in fact “report themselves” that Avastin improved

their quality of life. Once “a woman’s well-being, how she reports it herself” is not only totally synonymous with but also completely encompassed by the FACT-B score, the voices of all the women speaking for themselves during the public portion of the hearing are silenced, dismissed as not part of the “best instrument out there” or any “validated instrument.”

After this complete elision of actual women’s voices behind the calculable instrument preferred by the bureaucracy, Dr. Wilson, another ODAC speaker, completes the reformulation. He derides response rate as an “arbitrary number.” He says that it is quite possible—that all oncologists know, in fact—that patients can have reduction in symptoms without “hitting a response endpoint” and without “a bona fide PR” (measurable response endpoint). However, the truly important statement he leaves for the end of his speech. He sums up the debate about quality of life by saying, “So I think we’re back to ground zero in terms of, we have no evidence that the treatment arm improved quality of life.” Over the course of five consecutive statements by the ODAC speakers, “relief of symptoms” has become “FACT-B scores,” then “a validated instrument,” then “best instrument out there.” Then the *instrumentality*—the modality that would remind the hearer, or maintain in the record, the fact that the FACT-B is a human instrument used in a particular situation—is elided when the “instrument” *becomes* “a woman’s well-being, as she reports it” as the two are used synonymously. From there, it is only one step to Dr. Wilson’s statement about “quality of life.” What was originally a question about the mathematical correlation between two measurements in a single clinical trial became a correlation between the drug Avastin generally and quality of life generally, leading through incremental reformulations to an incredibly

strong claim for facticity, the statement that “we have no evidence” that the treatment “improved quality of life.”

Another aspect that is rhetorically interesting here is that the ODAC speakers achieve this through reformulations of both their own and others’ statements. They reformulate each other, such that each statement made by an ODAC speaker is simply a restatement, in slightly stronger terms, of the same claim made by the previous ODAC speaker. However, they also reformulate the Genentech representatives’ statements, *seeming* to simply restate what each of those speakers says (using “So . . .” statements often to leave that impression), but in fact restating what the Genentech representatives have said in such a way that it supports their own, not Genentech’s, interpretation of events. And more than this, they manage, without ever actually addressing or mentioning the public speakers (who are clearly not the audience, as they are never addressed, and only mentioned a few times, in the course of the entire hearing), to suggest that breast cancer patients’ own statements about their improvements in quality of life are neither “valid” nor “bona fide.”

It is clear, too, that this reformulation strategy has an immediate and important “pay-off” in terms of both the hearing and the official record. Each of the FLS-achieving reformulation series leads up to committee members’ voting on a given issue: there is a period of question-and-answer (like the one about quality of life outlined above), during which the ODAC committee asks questions and makes statements in a series that moves closer and closer to FLS for a particular claim, which then ends in the voting, during which each panelist must not only vote but must provide a rationale for his or her vote. It is here that the “pay-off” of the FLS reformulation strategy becomes apparent: in every

case, on every vote (there are four issues on which the committee is voting), the claim about which facticity has been achieved during the debate about that issue is the single basis on which each and every one of the voting members claims to base their (unanimous) decision.

After the FLS reformulation sequence outlined above, for example, each of the voting members votes “yes” to the question, “Does the available evidence on Avastin demonstrate that the drug has not been shown to be effective for the breast cancer indication for which it was approved?” Because the data have already been discussed (and the CDER committee ensured that only the calculable data, and only the interpretations of that data made by FDA-approved experts, would be admissible), the only question left is the one raised by both the public speakers and Genentech: the quality of life question. In other words, the only possible means for achieving a “no” vote on this question—the vote the patients and other public speakers, as well as Genentech, would like to see—is to show that Avastin is “effective” in some other way than improved survival. And the only other possible benefit of value is quality of life. This is why, in seeking to ensure their predetermined outcome, it is so important for ODAC to destroy the validity of the quality of life claim. Thus, it is telling that in answering this question about whether Avastin has been shown to be effective, ODAC does not outline the evidence but moves immediately into the debate about quality of life, using their opportunity to ask questions and to speak without being questioned to achieve FLS for a definition of quality of life that they know will provide the “no” answer they want to the “effectiveness” question they are being asked.

After the reformulation sequence, then, how does the “pay-off” in terms of the voting and the record show up rhetorically? It appears as a series of increasingly strong references in the voting members’ “rationale” statements, references to the very concept of quality of life that has just been constructed into fact by a series of statements in precisely the way Latour indicated. Dr. Freedman makes, first, an oblique reference to the quality of life issue in his rationale, saying that he voted yes (that Avastin is not effective) because “the totality of the data do not show a clinical benefit in the absence of anything else that we can get our hands around” (p. 236). The “anything else” referred to here is quality of life—the only alternative to clinical benefit that could change the vote on this question. The next voting member, Dr. Compagni-Portis, strengthens the statement with an explicit reference, tellingly prefacing it with the statement “I voted yes for the same reasons,” a statement that suggests she will say “the same thing” in different words—that she will be reformulating. She says that she voted against the drug because in addition to lack of clinical benefit, “we don’t show any improvement in quality of life,” a stronger, more explicit statement than the previous voter’s that she poses as a restatement of “the same reasons” (p. 237).

The subsequent voting members continue this process, each repeating some form of the phrase, “I voted yes for the same reasons” (pointing to a reformulation in process), then providing increasingly strong statements of the quality of life claim that the group had achieved facticity for during the questioning sequence. Dr. Logan notes that the outcomes in the studies have “questionable clinical relevance” and then adds that there is “no evidence of a benefit in quality of life” (p. 237) a stronger, more FLS-achieving statement than Dr. Compagni-Portis’s because it removes the modality referring to

human production (“we don’t show”). Finally, Dr. Sekeres says that he defines efficacy as “progression-free survival of significant magnitude couple with a quality of life advantage or an overall survival advantage, and Avastin didn’t achieve either of those definitions for efficacy” (p. 238), a statement that removes even the modality that refers to “evidence” and states the strongest claim of all, that the drug Avastin (not just these studies) did not achieve (rather than just did not show) either definition of benefit, including the quality of life.

That fact that the question-and-answer sequence in which the ODAC committee members incrementally achieve FLS for a particular statement—here, a particular definition of quality of life and the related statement that that definition was not met with Avastin—has an incredibly important “pay-off” in the hearing points not only to the power of ODAC to determine the nature of evidence and to arrive at its predetermined outcome (the outcome which most of the members have already publicly supported, remember), but points also to the record itself as the most important “audience” of the hearing. This is clearly so, since the final decision about Avastin’s breast cancer indication is not actually made in this hearing, but by another member of the bureaucracy not even involved in the hearing and higher up the hierarchy than anyone in the hearing: the FDA commissioner. The transcript is the only part of the hearing that will become part of the permanent record, and the votes of the committee members are the only part of that transcript that the commissioner officially takes into account in making her decision. Thus, the achievement of FLS for particular views and claims during the final portion of the hearing—the question-and-answer portion in which only the ODAC members may pose questions and make claims—is incredibly important in setting up a unanimous and,

because of the achieved FLS, essentially unquestionable basis on which the voting members can base their predetermined and unanimous decisions. The importance of that FLS is clear from the fact that the voting members use the claim for which they have achieved FLS *as* their rationale, and from the fact that the attempt at FLS for that claim continues and strengthens even as the voting rationales are stated. We will see this same FLS-achieving sequence, and the same “pay-off” in the voting, in the next section about implicit collusion between the CDER and ODAC committees.

Although this same process is used over and over during the final portion of the hearing—the portion during which the ODAC speakers get to ask questions and vote but need not answer any questions themselves—this example is the longest and has the most detrimental impact, as it eliminates the last argument that the public speakers and Genentech have: that women’s own statements, made in that same room, about their own improvements in quality of life, should count as valid evidence of benefit. The ODAC speakers subtly, incrementally, and powerfully reformulate that notion out of existence, leaving in the record the final official statement, that there is “no evidence that the treatment arm improved quality of life.” From that moment, the unanimous votes against Avastin on each of the other questions are not only not surprising, they are inevitable.

Reformulation and Collusion

The current committee system in place in the FDA began to take shape in the early 1960s, partly in response to the very public Thalidomide tragedy and partly in response to increasing public pressure to test all drugs available on the market. The 1962 drug amendments to the Food, Drug, and Cosmetic act “required FDA to assess all new drugs for effectiveness, as well as safety” (Rettig, Earley, & Merrill, 1992, p. 47), an

increase in workload and required expertise that threatened to completely overwhelm the FDA's capacities. Testing for effectiveness requires the entire several-stage process that now characterizes the FDA, with safety testing first (usually in animals and then in small groups of healthy human subjects), then comparative, double-blinded trials with many subjects with and without the disease in question. Moreover, the new regulation called for the FDA to "reassess for effectiveness nearly 4,000 prescription drugs that had been introduced to the market between 1938 and 1962—before proof of effectiveness was required" (p. 48). The FDA "responded by seeking external advice from the National Academy of Sciences-National Research Council (NAS-NRC) on previously marketed prescription drugs, establishing its own review committees for over-the counter drugs, and extending such committees to new prescription drugs" (p. 48). In other words, the FDA found itself suddenly in need of hundreds more experts, in dozens of fields of expertise—a collection of expert scientists it could neither afford nor maintain on its own. For a period, "ad hoc advisory committees" were used to fill the gaps (p. 48). These were suspended and then reactivated more than once over the course of the 1960s, until in 1969 Dr. Charles Edwards, as the new Commissioner, reactivated a number of standing committees and paved the way for the current system (p. 49).

During the years following the sudden requirement that the FDA test all old and new drugs for efficacy, the agency had to accept the recommendations of the outside committees simply because of the massive amount of work to be done. That reliance on the committees' decisions has persisted. "Although the reports of the Drug Efficacy Study [the reports of the early committees' work] were only advisory in the sense that FDA retained both the authority to disagree and the responsibility for implementing all

decisions,” as the *Institute of Medicine*’s report on FDA committees puts it, these reports “were often decisive in the agency’s decision making” (p. 51). The same is true today in the sense that the report—the record—of an advisory committee’s decision is almost always decisive, with the FDA disagreeing with an advisory committee report only very rarely since the 1962 changes (usually for obvious political reasons, as when the FDA approved Aspartame over the advice of its committee and the actions of its European counterparts). Later, certain committees came to operate essentially within the FDA itself, despite still being labeled “advisory.” CDER (the Center for Drug Evaluation and Research), for example, is now effectively an internal unit within the FDA staffed with full-time FDA employees, and it itself calls upon outside committees of experts when necessary to create either the reality or the appearance of independent, outside opinion. This is the role of ODAC—the Oncologic Drugs Advisory Committee—a committee made up of practicing oncological specialists who are not officially employed by the FDA and who provide, in theory, unbiased external recommendations.

However, the public (and pharmaceutical companies) often perceive the “external” advisory committees as operating in collusion with the internal agencies and the FDA generally. In this section, I will argue that certain of the ODAC committee’s FLS-achieving sequences, employed during the question-and-answer session and then cemented during the voting and rationale statements, suggest that the ODAC panel assembled for the Avastin case is invested in supporting CDER’s statements and claims by providing FLS for them after they have been opened to uncertainty by Genentech. Although this certainly cannot prove any kind of collusion between the internal and external committees of the FDA in any broad sense, it does suggest yet another rhetorical

explanation for why the decision of the ODAC committee appears to be predetermined and why, more broadly, the public does not trust the “transparency” of the open hearing.

The most obvious—and important—moment in which such an apparent collusion exists is during the first moments of the ODAC question-and-answer sequence, when the panel begins its work toward voting on the very first question, “Does the available evidence on Avastin demonstrate that the drug has not been shown to be effective for the breast cancer indication for which it was approved?” The very first ODAC speaker to address this question, Dr. Curt, reminds his hearers that Genentech has essentially claimed that the FDA has been inconsistent, granting accelerated approval (and thus approving the “confirmatory trials” at issue in the hearing) despite a marginal (6 to 5) vote against Avastin’s breast cancer indication very early in the process. However, Dr. Curt is not rehearsing Genentech’s argument to give it credence or value, despite saying that he can “actually understand the sponsor’s impression.” Instead, he is setting up CDER’s representatives to be able to respond to the charge of inconsistency during a period of the hearing in which Genentech cannot say anything unless directly asked—meaning that whatever CDER says in response to Dr. Curt will stand unopposed. At the end of his statement rehearsing Genentech’s inconsistency argument, Dr. Curt says, “So, Dr. Midthun [the moderator], I wonder if you could ask the agency to set these observations in context and to comment on whether the thinking here has actually evolved” (FDA, 2011b, p. 209).

The phrasing of this sentence is incredibly telling. In the first place, Dr. Curt refers to “the agency,” implying a separation between his own ODAC panel and the FDA (as represented in the hearing, officially, by CDER). Second, rather than asking the

agency's representatives to respond to the accusation of inconsistency, he asks them to "set these observations in context," a statement that suggests that Genentech's accusation is not a valid point but a misunderstanding of the context of the situation. Finally, Dr. Curt subtly suggests that the agency can take this opportunity to claim that it has *not* been inconsistent and that it will not be challenged: by asking the agency to comment on "whether the thinking here has *actually evolved*," he is implying that the thinking has *not* actually evolved—that the agency has not been inconsistent and now has the opportunity to say so. That the CDER representatives are aware that they are being given this opportunity is clear from their response. Dr. Pazdur immediately takes the opportunity to provide the agency's explanation for what appears to be inconsistency. "At that time [the time of the early vote]," he says, "we had very preliminary evidence [...] We were under the impression that a full dataset was going to be coming and that we would make a decision on the clinical benefit, obviously, at the time of receipt of the entire database" (p. 210). In other words, the true "context" of the apparent inconsistency is the context of Genentech's poor or limited evidence, not the agency's change of mind. The use of the word "obviously" here simply cements the claim that the agency could not have been expected to make a final or quotable decision until the "full dataset" was available—meaning that it is also "obvious" that any decisions made earlier than the receipt of that dataset cannot be used as evidence.

In other words, the very first move of the ODAC committee is to provide CDER the opportunity to respond—without fear of correction from either ODAC or Genentech—to the most damning claim yet made by Genentech's representatives, that the agency has been inconsistent in its decision making. Once CDER's explanation has

been made, the ODAC committee not only never questions it, but immediately moves on to its FLS-achieving question-and-answer sequences, each of which (as noted above) leads to a particular vote and provides the single key support for that vote, and thus for the record itself. However, whereas in the previous section, we examined in detail an FLS-achieving sequence that opposed Genentech and created facticity for a particular measure of quality of life that would silence both Genentech's and the public's representatives, here, we will examine two sequences in which the ODAC committee uses FLS-achieving reformulation sequences to create facticity for statements that accord very closely with the CDER claim that the "total dataset" must be examined, rather than any promising results from the E2100 study, and that the "totality of the data" does not confirm E2100—the single most important claim underpinning the CDER argument for withdrawal of accelerated approval.

In terms of rhetorical structure, the reformulation sequences all work through the same three stages by which the quality-of-life reformulation sequence occurred: first, the incremental reduction of modalities around the claim for which FLS is being achieved; second, the culmination of that incremental reduction into the use of the claim as a presupposition, the strongest rhetorical form of FLS because it is a way of using the claim in a sentence so as to assume that that claim is *taken for granted* and can be built on; and third, the use of that same claim as the key basis for the ODAC member's votes during the voting and rationale period for each question. The difference here is that each of the reformulation sequences I will address here begins with a question posed by ODAC to CDER that provides CDER an opportunity to respond to a criticism and, in so doing, set up the claim that ODAC will reformulate into FLS—a form of rhetorical collusion that

seems to support the public's and Genentech's perception that the ODAC has already predetermined its answer in favor of the FDA and is not truly operating as an "outside" committee.

The first FLS-achieving sequence occurs directly following the question and answer I just outlined, in which ODAC provided CDER the opportunity to respond to Genentech's critique that the agency was inconsistent. CDER's response was based on their central claim, that the "full dataset" or "entire database" had to be examined as a single entity, rather than, as Genentech and the public suggested, looking at E2100 separately to determine what about that study might suggest potential benefit. It is telling, then, that after providing CDER this opportunity, the ODAC speakers then take up the "totality of the data" argument and move from there to create FLS for CDER's own claim, that the totality of the data demonstrate that E2100 has not been confirmed.

Directly following CDER's statement that the real decision would be made, "obviously, at the time of receipt of the entire database," ODAC's Dr. Wilson makes a statement of his own. He says, "I think that what ODAC was asked to look at, at our last meeting, was the totality of the data, because at the end of the day, I believe what we're here to adjudicate is whether or not we feel that the original study has been confirmed" (p. 210). This statement does three things. First, it restates CDER's point about the "totality of the data" as the correct object of evaluation (as opposed to Genentech's and the public's argument that E2100 should be viewed by itself as a promise of benefit, at least for some users). Second, Dr. Wilson's statement connects the "totality of the data" with the question of whether "the original study was confirmed," setting the stage for the claim that will achieve facticity—the claim that *because* the totality of the data must be

examined, the original study is *obviously* not confirmed. Finally, Dr. Wilson's statement introduces this claim in such a way that it is surrounded by modal statements that suggest that at this point, when it has just been picked up from CDER, it has yet to achieved FLS. Dr. Wilson notes that he "think[s]" that the totality of the data is what they are supposed to "look at" and that the question about confirmation is "what we're here to adjudicate," all statements that very clearly place both claims in the context of human production and make them appear highly debatable.

Once Dr. Wilson has adopted these topics from CDER, however, they are quickly picked up by subsequent ODAC speakers and, in the exact series of steps laid out above, incrementally moved toward FLS. Dr. Wilson himself, after a relatively long discourse on what the role of the clinician should be, returns to the same questions with a slightly stronger claim: "it's difficult to look at these as confirming [...] E2100" (p. 211-212). The next ODAC speaker, Dr. Logan, moves immediately to achieve FLS for one of the claims—the main one introduced by CDER, in fact, the claim that the totality of the data must be the basis for decision making. "Right now, given the totality of the data," he says, "there is no data that Avastin extends the lives of women with metastatic breast cancer" (p. 212). Here, not only is "the totality of the data" (its meaning, interpretation, and so on) "given" and therefore no longer questionable, but the statement makes a strong implicit claim for the use of that "totality" in making the final decision. It is necessary to achieve FLS for this use of the totality of the data in order to build upon it the other claim, that this totality indicates that E2100 has not been confirmed. Dr. Logan's speech moves directly toward that aim, culminating in the claim that the subsequent trials "have all failed to confirm the magnitude of benefit" seen in E2100 and

that these trials show “a substantial reduction in the clinical benefit compared to what was original seen in the E2100 trial” (p. 214). Note that these are strong claims, but that they still maintain modal statements: the totality of data have not confirmed the “magnitude of benefit” (a measurement and therefore a reference to the studies that produced the data), and there is a “substantial reduction in the clinical benefit” in subsequent trials. Both of these suggest that E2100 has been disconfirmed, but both also do not make that claim completely; they simply argue that the total data show a *lower* benefit than E2100. These statements retain, in other words, precisely the modalities Latour describes as opening a claim to debate and reducing its facticity.

Thus, the incremental move toward FLS is continued by the next speaker, Dr. Balis, who explicitly replaces the “lower benefit” argument of Dr. Logan with another, stronger one: “I think that this question could have been worded in two ways. The other way it could have been worded is do these two trials invalidate the results of the first study?” (p. 215). Here, he moves from Dr. Logan’s claim that the *level of benefit* in E2100 has not been reproduced, to a much stronger statement that the study itself *is invalidated* by the subsequent findings—the totality of the data. And then, later in the same speech, he makes the final move to absolute FLS for the claim that E2100 has not been confirmed by using that claim as a presupposition on which to build a further argument: he asks “whether we continue to believe the results of the first study, and therefore think that, at least in one setting, there’s potentially some benefit, or do we take the data as a whole here and say that, since we couldn’t confirm that in the additional studies, then there must have been something wrong with the first one” (p. 215). Note here that, not only is he repeating the connection between using the “totality of the data”

and disconfirming E2100 (CDER's original claim in this sequence), but he is also using a very complex sentence structure. The first half of the sentence is a highly mitigated hypothetical: *if we believe* the results of the first study, we should *think that*, in *one* setting, there's *potentially* some benefit. The second half of the sentence, however, operates as a strong claim with the most important element embedded as a presupposition: "we take the data as a whole," and "*since* we couldn't confirm benefit," then "there must be something wrong" with E2100. The "since we couldn't confirm" presupposition is buried in this complex sentence structure in such a way that it is absolutely taken for granted, not only as a basis for the claim that there must be a problem with the original study, but as a grammatical basis for the rest of the sentence. FLS has been achieved for both the connection between "totality of data" and disconfirmation, and the claim that E2100 has been disconfirmed.

In the final step of the process, these two claims (introduced, remember, by CDER when ODAC gave them a unique opportunity to state their position without opposition) become the basis of each of the voting members' voting rationales on this question. When asked to provide their rationales for their (again unanimous) votes, each voter supports his or her decision on the basis of these same claims. "I did not feel," the first voting member says, "that these two studies confirmed clinical benefit" (p. 228). The next voter builds on this (again claiming to have "the same reasons"—one of our now-familiar cues that a reformulation will occur), saying that "I felt they did not verify the magnitude" of the first study (p. 228). The next voter says that the subsequent studies "did not confirm E2100" (p. 229); the next claims that the subsequent studies "failed to confirm the magnitude of benefit that was seen in the original study" (p. 229). The next

voter expands on the idea: “the follow-up trials, which were supposed to have been confirmatory, did not confirm the magnitude of progression-free survival” (p. 229). And the final voter agrees: the data “wasn’t enough to validate or verify the outcome of the first study” (p. 230).

It is important to note here that they are answering a question that is phrased so that they could have answered differently; it does not ask about confirming E2100 specifically, but about verifying the *clinical benefit* of Avastin for breast cancer. It was neither inevitable nor necessary that the ODAC speakers adopt the approach of CDER to this question, the approach that connects looking at the “totality of data” with the finding that E2100 is “disconfirmed” or “invalidated” as a study. In fact, the validity of E2100 is not necessarily even part of the question; CDER is interested in having E2100 invalidated in large part to oppose the idea that led to the beginning of this sequence, the idea brought up by Genentech that claims that the FDA *was* convinced by E2100 and has only changed its mind about Avastin because the agency is being *inconsistent*. In order to demonstrate that it is not inconsistent (and thus to validate its bureaucratic procedures in a larger sense, not just its decision on Avastin), the FDA must show that, first, the original E2100 study is not representative of the “totality” of the data, second, that that totality must be the basis of decision making, and third, that the totality of the data (which the FDA “obviously” had to wait for before making a final decision) proves that E2100 was itself flawed—which explains why the FDA *appears* to have been inconsistent but was actually *tricked* by Genentech’s flawed study. In achieving FLS for these claims, and especially in doing so in direct and immediate response to CDER’s making these claims in the first place, ODAC is not simply answering the question it has been asked. It

is defining the question, and then answering it, in precisely the way CDER suggests when ODAC gives it the opportunity to lay out its ideas at the beginning of the sequence.

This same sequence occurs again with the last question, which is whether the FDA should allow Genentech to continue offering the drug while performing further research. Here, the CDER representatives are again allowed to set the agenda in response to a supportive offer of an opportunity to speak provided by ODAC. Dr. Wilson of ODAC poses the question thus: “May I ask CDER to comment on this [the question of whether to continue approval while studies are done]? Because, again, the stance with the accelerated approval has not been to do this, because it is not considered to be feasible, so are we being realistic here?” (p. 251). He could not be more clear in providing a supporting opportunity for CDER; he places the question in a context that suggests that what Genentech wants has not been done before and has not been considered “feasible,” then poses a question that, like the question in the previous example, offers CDER the opportunity to very easily present its own position without fear of reprisal. At the end of CDER’s response to this (pseudo-) question, Dr. Pazdur sums up CDER’s response: “On one hand, we’re saying, the FDA is saying, this drug is safe and effective in the proposed indication; and then on the other hand, we’re saying, let’s test the same indication to see if it’s safe and effective. It’s a paradox” (p. 252). Again, the CDER representatives are setting the agenda here, and the agenda they are setting is specifically one that argues that if CDER’s approach is not taken, the FDA will be undermined because it will appear inconsistent. So while, technically, this final question is a very different one—and while it is one of paramount importance to those women in the audience who are already taking and benefiting from Avastin—CDER is

nonetheless again being allowed to set the agenda for ODAC's question-and-answer sequence in a way that is explicitly about validating the consistency of bureaucratic decision-making procedures, *not* about Avastin or the women taking it.

Again, ODAC obliges by picking up on CDER's desired outcome and achieving FLS for a position that supports it: in this case, the claim that women taking the drug could be hurt because of the paradox that the FDA has approved the drug without actually knowing whether it is safe or effective, exactly the claim CDER wishes to be made. As Dr. Compagni-Portis (one of the ODAC members) puts it just after CDER's statement, "It just seems that we could have many years of women using this drug without proof of effectiveness or without monitoring the dangers" (p. 253)—a reformulation of CDER's "paradox" issue. This concept of potentially harming patients then becomes the single debated issue of this sequence, with Dr. Curtis for example asking Genentech whether they can identify any particular subsets of patients who are "least likely to have toxicity" (p. 255). Then, when Genentech does provide a plausible answer to this question, ODAC does something it does not do when CDER provides a viable answer: it gives the opposition a chance to answer, providing CDER yet another opportunity to express its own agenda. Finally, as they move closer to the vote, the ODAC speakers stop asking the other groups questions and begin to move toward FLS for the CDER-suggested claim that continued approval would be inconsistent because the FDA would be claiming safety and efficacy without actually having voted that the drug was safe or efficacious.

This cements itself into the final claim that continued approval has the potential to do harm because the potential adverse reactions are not completely known. As Dr.

Freedman puts it, “It’s a question of whether you allow the approval to continue and then potentially do harm to patients versus stopping it.” He also argues that although it might seem as if those patients with the most symptoms (those in the audience, for example, although he does not directly acknowledge them) would benefit most, “Maybe they could do worse, because they would have the disease plus the serious adverse events to deal with” (p. 259). Given that the entire question of the debate is *whether* these patients would have serious adverse events to deal with—and *whether* the “harm” Avastin might do them is worth the risk—the fact that Dr. Freedman takes “the serious adverse events” as a presupposed reality *and* a presupposed obvious reason not to take the drug indicates his clear alignment with the agenda set by CDER. And moreover, it indicates that ODAC’s answer to this final question has achieved FLS, just as the previous ones did, through a sequence of statements that have achieved facticity in a presupposition for a claim that was itself the question at issue.

That the purpose of these sequences is to support the FDA’s bureaucratic approach to decision making becomes clear at the end of this sequence, where several ODAC members make statements that explicitly support that approach. As Dr. Logan puts it, “I think it’s important that the label should reflect a current understanding of the benefit-risk profile” (p. 261); in other words, the important question is not whether some women might benefit from continued access, but whether the label on the bottle accurately reflects the vote of the committee. A few moments later, Dr. Wilson adds another layer to the argument, saying that “we have a standard and [...] we shouldn’t be changing that standard unless we have a very good reason” (p. 263). And lest anyone in the audience believe that, for example, patients’ own claims that they are benefiting

should count as a good reason, he continues and says that the two later trials “do not confirm the original findings, and, hence, the withdrawal is indicated,” reifying the procedural approach as the only one that produces valid and actionable results (p. 263).

Once more, the voting rationales of the ODAC members reflect both the FLS achieved around a particular claim *and* the fundamental connection between the claim that has achieved FLS and the original agenda set by CDER. Dr. Balis supports his vote by saying that “I think it’s contradictory, as we talked about, to conduct a study to show efficacy at the same time that you leave the drug approved for that indication” (p. 265)—a very close rephrasing of CDER’s original “paradox” statement. Dr. Sekeres speaks next, stating that “It gave me pause to continue to make available a drug for an indication when that drug hasn’t demonstrated the type of efficacy that women with breast cancer deserve and expose them to serious toxicities” (p. 265)—a rephrasing of CDER’s claim that strong evidence of efficacy and safety have not been proven. Dr. Logan, too, uses a similar argument, saying that “the benefit-risk profile is not favorable right now” (p. 266), and Dr. Compagni-Portis says that “women would continue to be subjected to an unproven treatment with serious risks” (p. 266).

What is perhaps most important to remember here, given that these claims appear so strong, is that the people for whom they are making this decision are in the room—the “women” who will be “subjected” to the treatment are in front of them and have asked to be subjected to it. It is left to the final two voting members of ODAC to indirectly respond to those women and to explain precisely how little their voices have been valued in the hearing. As Dr. Freedman put it (in the quote discussed earlier), “I struggled with this and struggled with this until just before the meeting” (p. 266)—in other words, he

struggled with his decision by looking over the materials provided by the FDA and the other “parties,” right up until the moment just before the first woman with breast cancer began to speak, at which point his mind was already made up. However, it is Dr. Wilson who makes the final and most telling statement, the one that indicates not only that the women’s voices have not been heard and that the patients and the public are not the true audiences, but also that the point of the hearing has specifically been to support a particular FDA-approved decision-making approach: “I would say to, also, patients out there with breast cancer that I think these have been extremely important trials, and that I hope that they look at all of the evidence and look to see that, in very large, randomized studies using other very potent taxanes, there was no evidence that this drug was of help to them” (p. 268). In the last moments of the hearing, then, the ODAC committee members finally recognize, in some form, the patients and patient representatives and family members actually standing in front of them and, rather than actually addressing them as an audience, speak about them in the third person, reifying the bureaucratic, calculable, rule-based approach to their diseases and arguing that the patients themselves should be so convinced of the bureaucratic approach at this point—because this approach has achieved such facticity through the final portion of the hearing—that the patients should walk away with some newfound awareness that they were wrong about their own diseases, wrong in thinking that they felt better, wrong in measuring their lives in baseball games and births and graduations, and should be *glad* that this drug has been taken from them. This is the ultimate achievement of Fact-Like Status for the bureaucratic approach to public health, when it is so taken-for-granted that human beings should ignore their own lives and experiences and accept it in their stead.

This is not to argue that it would be preferable to simply replace regulation with individual choice. Nor is it an attempt to argue that the public speakers and the women who claim to have been helped by Avastin are more correct, have a more valid understanding of disease, or are better positioned to make a decision about the drug than the scientists on the ODAC panel. Rather, I note the absolute rejection of the patients' perspectives on their own disease as a demonstration of the level of facticity the ODAC committee manages to reach in the record. Not only has it achieved facticity for its own (predetermined) decision, but it has, as far as the record is concerned, actually managed to achieve FLS for the position that the patients who spoke are by definition mistaken about their own conditions and experiences. In other words, this is not a sentimentalization of the patients or their experiences but a recognition of the achievement of the ODAC speakers in bringing about facticity for the correctness of the bureaucratic approach to public health. Here is where the "fake" in "fake democracy" truly occurs, when the bureaucracy *invites* speakers to present their opinions as citizens and stake-holders, then not only rejects but actually *nullifies* that participation in order to re-assert the value of bureaucratic approaches—and to re-assert their value not only for the bureaucracy but for the citizens themselves.

As a final note, I will admit that one possible argument against this interpretation of the final portion of this hearing is that CDER is simply correct—that their interpretation of the data is simply the right one—and that ODAC agrees with and supports that interpretation because it is the correct one. There are three reasons to consider this argument suspect. The first is that there is so little consensus about the data and their interpretation that it is questionable to argue that any particular interpretation is

correct. After all, other major drug review entities, including the EU’s equivalent of the FDA, have approved the breast cancer indication for Avastin using the same evidence. Furthermore, the debate in the hearing, as we have seen, is not even primarily *about* the data and their correct interpretation but about who should get to make the decision and how that decision should be made. On that score, the reformulations of the ODAC committee work very strongly to support the bureaucratic approach to public health, not just one interpretation of the Avastin data.

The second reason to be suspect about arguing that CDER is simply “right” is that the reformulation sequences never revolve around (or even particularly mention) data or evidence; rather, they are invested in attaining facticity for ways of measuring and ways of understanding—debates that, if won, will support not only this decision but the FDA’s entire procedural basis.

Finally, it is suspect to argue that, because they agreed about the meaning of the data, the ODAC committee members perfectly reproduce and reproduce, in each question and answer series, an FLS-achieving reformulation sequence, leading up to a presupposition, around a single item of debate brought up by the CDER committee when given the opportunity to do so *by* ODAC, which single item of debate in every case becomes the key lynchpin argument underlying all of the ODAC members’ individual voting rationales. The very fact that such a clear pattern develops is an indication that—whether or not they are doing so “intentionally”—the ODAC panelists are using rhetorical reformulations to elicit, then support, then achieve facticity for, CDER claims that then become the basis for the most important item of “record,” the votes themselves. The ODAC committee members’ own final statements indicate, as we saw, just how

completely those votes were already decided before the hearing ever began. Thus, the hearing itself was a process for achieving FLS for bureaucratic approaches to public health, and a large part of the rhetorical means of achieving that FLS is the series of incremental reformulation sequences that occur in the final voting and voting-rationale period.

Hearing Structure and FLS in the Record

By this point, it should be clear that the structure of the hearing itself supports the rhetorical moves being made by the ODAC committee members as voices of the FDA—and in doing so, supports the idea that the record, not the human beings in the room or in the public outside its walls, is the audience (standing in for the bureaucracy itself as the audience of its own productions, and producers of its own audience). Because they were already touched upon in previous sections, I will only briefly review these structural elements. In discussing them, it is important to remember that a rhetorical strategy is not either effective or ineffective in itself. The public, with its pragmatic and values-based appeals, certainly uses rhetorical strategies that are persuasive with many, many listeners. Their appeals in the hearing are persuasive and consistent, building a viable alternative method of health decision making that (as the conclusion will argue) is seen by many doctors and oncologists as not only useful but correct. However, those effective, persuasive, coherent arguments are totally ineffectual in the hearing, unable to compete at all against the rhetorical reformulation strategy of the ODAC committee. Again, this is not because the reformulation strategy has inherent value, because it is inherently “more persuasive” or more effective, or because anyone in the room actually subscribes to the idea that reformulations toward facticity should drive decision making. Instead, the

structure of the hearing provides the opportunity for reformulation toward FLS to be the most effective strategy for a particular set of speakers at that particular moment, while simultaneously reducing or eliminating the powerful effectiveness of the public speakers' rhetoric by repressing their voices and, even more importantly, allowing ODAC to make the repression of their voices part of the official record.

The structural elements in favor of ODAC are significant. In addition to being the only people in the hearing who are allowed to vote—and thus the only people whose statements or claims are captured in the part of the “record” that the Commissioner uses to make her final decision—the ODAC representatives are also allowed to ask questions of any other speaker while essentially avoiding having any questions asked of themselves. Perhaps the most important structural support, though, in terms of the effectiveness of their rhetorical strategies in determining what shows up in the official record, is that the ODAC speakers are allowed to speak last, posing questions to those they wish to hear from and either allowing or disallowing various stakeholders to respond to what has been said. As Dr. Midthun, the moderator of the hearing, puts it in her instructions about the final portion of the hearing: “Only the advisory members and I will participate in this discussion. If advisory committee members have questions of Genentech or CDER, please direct your questions to me, and I will then direct them to the parties” (p. 204). As we saw above, the direct effect of the limiting of this final discussion to the advisory committee members and the moderator is that the ODAC representatives have total control over who may speak, and they can use their questions (and do use them) to set up and encourage particular interpretations and statements that support their own predetermined outcome.

This opportunity to speak last and to control who gets to speak and on what topics in the final moments of the hearing is absolutely essential for the effectiveness of the reformulations the ODAC speakers use to achieve FLS for their own decisions and for bureaucratic decision-making procedures more generally. If this final comment period were open, or if actual debate were allowed, Genentech (although not the public speakers who, as “nonparties” are not allowed any form of participation after their opening session) could re-introduce into that debate precisely the uncertainties about the FDA’s data, interpretations, and procedures that they had managed to achieve during their own presentation. That this introduction of uncertainty was successful, at least to the extent that it might indicate a different course of action than the one predetermined by the FDA and ODAC, is evident in the fact that ODAC’s first move during the final question-and-answer session is to bring up the most damning element of that uncertainty (the accused “inconsistency” of the FDA’s decisions and procedures) and not only offer CDER the opportunity to respond but also pose the question in such a way as to make it clear that CDER will not be opposed.

The achievement of FLS for particular claims in science is always a give-and-take process as described by Latour and Woolgar: peer review, competing articles, new data, and other factors are always re-opening and re-closing the “black box” of facticity. As the Latour cartoon described at the beginning of this chapter suggests, closure is never permanent, modalities of production are always being introduced and erased, and FLS is always being negotiated, even for claims that appear to have been decided absolutely. However, that process must be supported—as in the larger scientific community it is (ideally) supported—by structural elements that allow interaction, debate, and

questioning. It is precisely this structural allowance that is *not* present in the FDA hearing, and in fact the opposite exists: a structure that supports the unquestioned achievement of FLS for certain predetermined claims and procedures that are favorable to the bureaucracy. In this sense, it is irrelevant whether the FDA makes the correct choice or not; the structure of the hearing is such that predetermined outcomes will be reached—a set-up that runs counter to effective scientific work as Latour (and others) outline it.

In addition to being counter to the working of truly investigative science, the hearing structure that supports the predetermined FDA conclusions is also precisely what the public is perceiving when it claims that the hearing is unfair. Furthermore, in addition to providing structural supports that provide the opportunity for FLS production for FDA claims, the hearing also uses structural restraints that ensure not only that the public will not be able to participate in the hearing as true parties but also that the public's rhetorical strategies will be in essence "debunked" or delegitimized in the official record. In the first place, the public speakers are never allowed any form of interaction; they cannot pose or answer questions, and after the brief period of public speakers' statements at the opening of the hearing, they are never allowed to participate in any way in the rest of the hearing. Each speaker is only allowed 3 minutes, while none of the other speakers, from any of the other groups, is given a time limit in this way. As one public speaker puts it, "Giving us three minutes is a disgrace that diminishes the credibility of this FDA and shows disrespect to the breast cancer victims" (p. 64). In fact, this speaker's time runs out before he is allowed to finish, and as with the other public speakers, he is simply cut off; the microphone turns off, and the rest of his comments are

both inaudible in the hearing itself (and in the video recording) and simply marked as “[Time runs out]” in the official record (p. 65).

It is not enough, though, that these speakers are given limited time and almost no participatory opportunity. In order for the FDA’s bureaucratic procedures not only to win in this case but to exist in the record as the only valid and validated ones, the public speakers’ (very effective) rhetorical strategies and claims must be invalidated in the record. This is where ODAC’s ability to speak last becomes particularly powerful—and causes particular resentment among the patients and patients’ groups who are in the hearing. As we have seen, the ODAC speakers use their question-and-answer session not only to create FLS for their own claims but to explicitly “debunk” any claims to validity on the part of the public speakers’ statements, claiming four times during that last portion of the hearing that “anecdotes are not evidence” (p. 242) in one way or another. We also saw that the ODAC speakers used their reformulations to oppose the public speakers’ concept of quality of life as something that can be defined individually. And moreover, the very last statement of the very last ODAC speaker is a kind of lesson to the public speakers, literally informing them that, whatever their personal experience, the ODAC speaker hopes that they have now learned that there were no benefits to Avastin. The public speakers—the actual patients with breast cancer whom the FDA claims to be helping and supporting—are in every way structurally relegated to “nonparty” status.

The structure alone does not ensure that the FDA’s predetermined decisions will be reached or that bureaucratic approaches to public health will be reified. Similarly, even an effective rhetorical strategy such as ODAC’s use of incremental reformulation toward FLS cannot be effective—and certainly cannot be so effective as to overwrite and

“debunk” the rhetorical strategies and appeals of all other speakers and participants—when used within a system or process that allows true open debate. The combination of the two, with the structural elements of the hearing supporting and creating the opportunity for the FLS-achieving rhetorical reformulations and the reformulations reifying the very structure that supports them, is, however, incredibly effective—devastating, in fact, to the public speakers, despite their own effective rhetorical strategies and widely accepted interest- and values-based legitimizing rhetoric.

Conclusions: Reformulations, Inevitability, and Correction

Before the hearing even began, Genentech argued that its outcome was inevitable because the ODAC panelists had already both voted on Avastin and publicly defended their votes, giving them a very strong interest in proving themselves correct. Whether it was because they had publicly stated their opinions or for other reasons, the outcome certainly does appear to have been inevitable—and certainly also appeared that way to the public speakers, patients’ representatives, and others who spoke out against the hearing structure both during their presentations and before and after the hearing itself. However, if the outcome was inevitable, the question for rhetorical analysis becomes: *how* did the FDA committees, and especially the voting committee, ensure the outcome they desired? As I have argued in this chapter, they did so by combining a very powerful rhetorical strategy (incremental reformulations toward the achievement of FLS for predetermined claims and the decision-making procedures that support them) with a structure that allowed that rhetorical strategy to remain unchallenged.

All of this also supports the claim I made earlier, that the true audience of this hearing is not the public, nor in fact *any* of the people actually sitting in the room over the

2 days of the hearing. Rather, the true audience is the record, the official bureaucratic memory. The FLS-achieving reformulation strategy ensures not only that the predetermined decision will be reached in this particular case, but that bureaucratic approaches to public health generally, the structure of the hearing, and the calculable definitions the FDA accepts as evidence will all also be validated by the record—and thus, future speakers and actors for the bureaucracy will be able to draw on that record as validation of their continuation of the same strategies, even if, as is so often the case in bureaucracy, the actors themselves have changed through turnover. As the official memory of the bureaucracy, the record is both the outcome and the support of each bureaucratic action, participating in the circular legitimization outlined in Chapter 3.

The “correction” element of reformulations is important here as well, as the public is reframed in the final reformulations sequence not only as a nonparty but as a recalcitrant and misinformed entity that must (indirectly, since it is never directly addressed) be corrected in its “misinterpretations” of medicine, health, and public health decision making. In this sense, also, the “record” is the true audience, since it is clear that the public speakers themselves are never actually convinced that their entire concept of themselves, their disease, and their reaction to the drug Avastin has been misinformed and incorrect. What becomes clear in the reformulations sequence, then, is that the people who are being talked *about* are not the people being talked *to*, and that persuading or convincing any human audience is in fact irrelevant. Rather, the only important outcome of ODAC’s rhetorical maneuvers is to achieve an appearance of facticity for certain ideas, upon which future decisions can be based because these ideas now have the status of being “taken-for-granted.” Each statement supports the existing record; each

record in turn supports future statements. This is particularly interesting in terms of rhetoric because it indicates that no form of persuasion, no convincing of any audiences, and no achievement of consensus, compromise, or even grudging acceptance is necessary to make a rhetorical strategy incredibly effective. In the case of bureaucratic rhetoric, any strategy is effective if it supports and is supported by the official record, the actual—impersonal—“audience” of the bureaucracy’s statements.

CHAPTER 5

CONCLUSION: BUREAUCRATIC RHETORICS AND THE ATTENUATION OF COMPLEXITY

It is important to remember, before delving more deeply into the potential implications of the bureaucratic rhetorical strategies explicated here, that it is in no way the purpose of this project to argue that the FDA made the “wrong” decision about Avastin. It is precisely because gathering and analyzing data and making decisions about the subtle, sometimes minute risk and benefit effects of modern pharmaceuticals involves so many complexities, that it is almost impossible to know whether a “correct” decision has been made. It is difficult even to argue that a correct decision exists for such a complicated question. In fact, the very complexity of attempting to identify the “facts” about Avastin raised some of the most important rhetorical questions addressed in the analysis sections above, particularly questions about how the FDA achieves such solid facticity for a position for which the facts are too inconclusive to make strong claims.

Given that the FDA’s counterparts in other parts of the world—most notably the European Medicines Agency—have approved the breast cancer indication for Avastin on the basis of the same studies and data, and given also the amount of debate in this hearing about which endpoints to consider (some showing benefit for Avastin, some showing none), it would be nearly impossible to determine the “truth” about Avastin’s value for breast cancer patients. For this reason, it is not my purpose here to question the FDA’s

decision, but rather to answer questions about the rhetorical strategies such an agency uses when faced with such a decision. In other words, I have attempted, through my analysis, to identify the rhetorical strategies that legitimize and characterize bureaucracy and the effects of those strategies on the relationship between U.S. bureaucratic institutions and the publics they are intended to serve.

It is also important to note that this project does not advocate a return to a pre-scientific or a move to an antiscientific approach to public health. The importance of maintaining some regulatory control over the composition of pharmaceuticals, particularly in an age in which it is increasingly possible to create new, never-before-seen chemicals and sell them as medicines, is clear. One need only remember that the FDA was created in response to the “patent medicine” era, in which drugs could be sold that contained any kind of chemical, with no labeling requirements and no testing of any kind, to remember that regulation in this area is largely positive. Certainly the antiscientific, antigovernment movement that calls for an end to all regulation is not the answer. However, as I will discuss below, the context of that regulation has changed so dramatically since the inception of the FDA that the agency’s continued adherence to particular approaches to decision making, appropriate as they were to an era in which antifreeze could end up in cough medicine, will not necessarily work in an era of decisions as ambiguous and complex as the Avastin case. The effect of such continued adherence, in fact, is problematic *because* regulation is and can be valuable. Because continued adherence to outdated notions about the availability of clear-cut facticity can lead to decreased public trust in the agency, the very concept of drug regulation may suffer if the FDA continues to justify its decisions on such bases.

In this concluding chapter, therefore, I will not dwell on the decision itself. Almost certainly, Genentech will continue to enroll clinical trials intended to repeat the findings of E2100 and support the company's claim that Avastin should be approved for the breast cancer indication. The drug may yet be approved for that indication. Alternately, new data could suggest that E2100 was in fact a fluke, and Avastin may be withdrawn for breast cancer in the countries in which it is now approved. Moreover, even though many insurance companies will no longer pay for Avastin for breast cancer patients, doctors do and will continue to prescribe it, at least for those patients who can afford to pay. The factual questions about Avastin and its uses in breast cancer treatment, in other words, are still far from answered. About the central question posed by this project, however—the question of what the FDA is doing, rhetorically, that is causing or contributing to decreased public trust even as the agency becomes more transparent—some conclusions can be drawn. This chapter will lay out those conclusions and, more importantly, some of their implications for the FDA, the public, the practice of medicine, and rhetorical theory.

Implications for the FDA

The implications of a decline in public trust are obvious as far as the FDA is concerned. Although it is clear that individual citizens and groups of citizens have little influence on the day-to-day decisions of the agency, it is nonetheless the case that, being authorized through the U.S. Congress, the FDA is indirectly answerable to the people. To date, the FDA has enjoyed one of the highest levels of public satisfaction and trust of any of the U.S. government bureaucracies, but that satisfaction and trust is waning rapidly. The Pew (2010) study mentioned in the introduction, tellingly titled “Distrust,

Discontent, Anger and Partisan Rancor,” indicates that the FDA saw a 17% decline in “favorable” ratings from the public between 1997/98 and 2010, the second highest decline after the Department of Education. The study also finds that Americans increasingly see government agencies as having the “wrong priorities.” This represents a significant shift even since the 1997/98 period, when the public’s primary issue with government was that it ran its programs “inefficiently”—a problem much more amenable to bureaucratic fixes. Moreover, the study found that a significant and increasing number of Americans believe that government agencies have, overall, a “negative effect on daily life”—43% in 2010, up from 31% in 1997/98. It is clear, in short, that the public’s trust in U.S. bureaucratic government agencies is declining, and it is declining in part because of a belief that those agencies do not have the right priorities¹⁶. Given that the hearing analyzed here became, in large part, a debate over priorities (the importance of maintaining and following bureaucratic procedure versus the importance of providing choices and options for patients), the agency’s continued insistence on proceduralism, calculability, and the other priorities and values of bureaucracy is almost certainly contributing to the public’s declining trust in and favorability toward the institution.

However, changes in medicine itself—innovations in medical procedure and pharmaceuticals, particularly for chronic and complex diseases like cancer—are likely to accelerate that decline in trust and also reduce even more the public’s patience with bureaucratic approaches. As Fran Hawthorne (2005) discusses in *Inside the FDA*, individualized medicines are already in development. These medicines are made from

¹⁶ However, clearly, this is not the only reason for declining trust in American democratic governance. See Wolin (2010), for example, on the concept of “managed democracy” and its effects on both the workings of the U.S. government and the public’s perception of it.

the individual tissues of sick persons. For example, a company called Antigenics has developed a process that uses material extracted from tumors to create individualized medicines containing specific antigens to fight individual tumors. This is considered an exciting and necessary next step in cancer treatment for exactly the reasons the public speakers at the Avastin hearing mention: every tumor is different, with different chemistry, physical make-up, and reactions to pharmaceuticals. Using the material from one's own tumor could allow for the creation of targeted drugs designed specifically for an individual's particular cancer, in essence an individualized vaccine against one's own cancer cells. However, such an approach is nearly impossible to test using FDA-approved procedures. As Hawthorne (2005) puts it:

For instance, in order to make sure that volunteers in experimental drug trials—and, ultimately, patients in the general population—are not swallowing something dangerous, the FDA obviously needs data from the manufacturer about the potency and safety of the drug being tested. But the agency goes a step further, asking manufacturers to explain how they will test their drugs to obtain the potency and safety data. [...] So the manufacturers have to provide details about the tests they use to check a drug—known as *assays*—even before the human subject can swallow the first pill or be injected with the first dose.

With a traditional chemical drug, measuring is fairly routine. However, vaccines are much more variable because they are made from living material, which is inherently inconsistent. And vaccines made to order from the patient's own tumor are even more variable, a totally new creature for the FDA. (p. 3)

Moreover, if each batch of medicine is made from the individual's own cells, then randomized clinical trials, the “gold standard” required by the FDA, are essentially impossible. The entire purpose and point of an individualized vaccine is that it will react with the individual's tumor in a way that it will not react with any other human tissue or tumor—and the tumor will react to that medicine in a way it will not react with anything

else. Giving the drug to a random selection of volunteers will provide no relevant information.

However, in a response that is typical of what has been demonstrated about bureaucratic approaches to public health in this paper, the FDA's response to Antigenics was to ignore the scientific research that supported the idea of individualized cancer treatments, as well as the "terrific unmet need" (p. 4) for the drug. Instead, the FDA asked, again, whether Antigenics could "document how it would test the safety of the drug that it was putting into its subjects" (p. 4). Then, because it was literally impossible for the new drug to be tested according to existing FDA procedures, the drug was "placed on partial clinical hold" indefinitely, meaning that "[n]o new patients would be permitted to try the vaccine" (p. 4). Given that the company argues that its new vaccination approach "could work for all cancers" and also "for neurological diseases, cardiovascular disease, infectious diseases, and conditions associated with aging" (p. 7), putting the development and testing of its technology on indefinite hold seems to run counter to the best interests of American citizens. Of course, such a statement from an officer of a company cannot simply be accepted at face value; nonetheless, if the response of the FDA continues to be strict and rigid adherence to its existing procedures, such new approaches to fighting disease through the use of individual tissues will never gain approval.

In the United States, that lack of approval means the drugs will never enter medical practice. That is, they will never enter medical practice unless the approval of the FDA becomes far less relevant than it is now—becomes, in fact, irrelevant to insurers, medical providers, and patients. Although the FDA's approach, as we have

seen, is far from perfect, such irrelevance is not to be hoped for. It would mean, essentially, a return to the unregulated medical free-for-all that led to the creation of the FDA in the first place. It is really for this reason, to avoid a return to a de facto unregulated pharmaceuticals marketplace, that the bureaucratic rhetoric of the FDA is particularly problematic. If an understanding of that rhetoric can help us understand why the FDA is losing ground in terms of trust and acceptance of its procedures, perhaps a shift in that rhetoric, a shift toward greater acceptance and validation of public and patient concerns, could help stem the anti-FDA tide.

It is also important to remember, in calling for a change in approach by a science-based regulatory agency such as the FDA, that the rhetoric and procedures of such an agency are neither accidental nor “natural.” The specific elements of the FDA’s bureaucratic rhetoric identified in this project, for example, have their origin in a very specific historical period—the late 19th century and the first decades of the 20th—in which a free-for-all, unregulated environment existed as far as medicines were concerned. Given that environment, the creation of strict legalistic procedures and safety tests was in line with the problem the agency was created to solve. In the sulfanilamide tragedy, for example, the problem was obvious, and its solution was equally obvious: every bottle of the toxic “medicine” was collected, the company was fined and put out of business, and the “elixir” was never sold again. Eighty years later, however, the issues facing the FDA are not so clear-cut. In fact, it is in part because they are not so clear-cut that the bureaucracy insists so heavily on its procedures; in the absence of any strong scientific evidence one way or the other, and in the absence of even a consensus among doctors and scientists about what the existing evidence means, the *only* basis for a

population-level bureaucratic decree is to declare that the decision is correct because procedure has been followed.

Avastin is an excellent example of the shift that has occurred in the FDA's purposes and the regulatory issues it must contend with since the 1930s. The early FDA was essentially a "policing" agency involved in ceasing the production and distribution of unsafe, unregulated medications; its purview was more interstate commerce than scientific research. Now, however, it is almost exclusively a scientific agency involved in the evaluation of complex research about the relative risks and benefits of pharmaceutical chemicals and biological compounds created in laboratories and never seen before (Carpenter, 2010). As noted above, multiple agencies around the world considered the same Avastin data and came to different conclusions. No two agencies, nor even any two groups in the FDA hearing, could agree on which of the possible "endpoints" should count as demonstrating (or not demonstrating) the benefit of the drug. Patients seemed to respond or not respond depending more upon their own chemistry and the biology of their individual tumors than upon the drug's innate characteristics. The data were so mixed as to make an actual determination of the drug's "safety and efficacy" essentially impossible, so the agency fell back upon its procedural rhetoric to support its decision. However, the procedures it fell back upon were those designed more than half a century prior to deal with clear-cut questions of safety before lab-designed biochemicals or individually-derived cancer "vaccines" were even conceived.

In short, the agency continues to use a bureaucratic rhetoric that simultaneously supports and is supported by procedural and calculable approaches that were created to deal more with issues of *malfeasance* than of biochemical innovation. The implications

of continued unquestioned adherence to this rhetoric are clear: declining trust in the agency's "priorities" by members of the public, increased difficulty in managing the far more complicated biomedical and pharmaceutical questions of the 21st century, and—particularly with the advent of the internet and the ability to purchase medicines online from overseas—potentially a return to a largely unregulated pharmaceuticals market.

Implications for the Public

As far as the public is concerned, the most important implication of this project is the indication of a breakdown between the (supposedly) democratic processes by which the government is intended to respond to the citizens and the actions of the bureaucratic agencies created to do the work of the people in that government. This breakdown is clear in the disconnect between the values-basis of the public speakers' statements—specifically their insistence on the overriding importance of individualism and choice—and the procedural, calculation-based claims of the bureaucracy. The effect of this breakdown is what has been described as "fake participation," in which a government agency appears to support democratic processes through the invitation of public participation in its decisions but in fact provides only an opportunity for members of the public to feel that they have had their say, without allowing them any true influence. As J. H. Snider (2010) puts it, "Fake participation occurs when governments seek the democratic legitimacy but not the accountability that comes with public participation" (p. 90). He goes on to note the value of fake participation for government agencies. "Fake participation," he writes, "is an element of the much larger and more troublesome phenomenon of fake democracy. The basic logic behind fake democracy is quite simple.

In the contemporary world, democratic rule has more public legitimacy than authoritarian rule” (p. 91).

Snider provides examples of five methods by which government agencies create fake participation. One applies particularly to the Avastin hearing: “Signal[ing] the futility of participating to those most likely to participate” (p. 96). Throughout the hearing, but especially in the FLS-achieving question-and-answer period at the end, the utter futility of the public’s “participation” in the hearing is signaled (implicitly) again and again. In the first place, the public is positioned literally on the other side of a bar and is referred to as the “nonparties.” The public speakers, unlike any other group or speaker, are given a time limit (3 minutes, barely enough time in which to introduce oneself and make one or two points), are regulated in their speech by a light system (green when they are “allowed” to speak, yellow when time is running out, red when their time is up), are actually cut off at the time limit (their microphones are turned off), and are never allowed to direct any questions to, nor be asked any questions by, the true parties. After their 3 minutes are up, they are simply ignored and never referred to, except in a few brief and largely derogatory statements (such as the repeated statement that the “anecdotes” heard from the public speakers do not count as evidence).

To add to the sense of futility, the FLS-achieving question-and-answer series at the end of the hearing achieve FLS for bureaucratic concepts and measurements that directly contradict the statements and beliefs of the public. In fact, these FLS-achieving sequences construct the public as novices who lack understanding of both the reality of the situation and the acceptable decision-making processes. As Judt (2010) puts it, members of the public “are made to feel inadequate” in dealing with governmental

institutions “as soon as issues of detail are engaged; and as for general objectives, they are encouraged to believe that these have long since been determined” (p. 172). This is the didactic effect of reformulations: to reinforce the idea that their participation in the hearing has been futile, the final FDA speaker (indirectly) addresses the public to “explain” to them that the hearing has—or should have—demonstrated to them that their own beliefs, feelings, and statements were incorrect all along. Without ever saying so outright, and indeed while maintaining the appearance of accepting and encouraging the public’s input, the FDA repeatedly makes it clear that that input has been and will continue to be futile.

Bureaucracy particularly encourages fake participation. Because a bureaucracy’s decisions are legitimized in a circular fashion—decisions must be made based on calculable, rule-based, procedures, which must be inscribed in the record, while that record is used to support those same procedures—there is no location, no opportunity, for input from outside, no matter how much participation there may appear to be. As was demonstrated above, bureaucratic rhetorics legitimize and are legitimized by internal experts who simultaneously are recognized as experts by, and gain their expert status from, the bureaucracy—again, no place exists for outside “expertise,” and in fact no other expertise can be or is recognized as such. In short, in bureaucratic interactions with the public, as we have seen in the FDA hearing, bureaucracy by definition comes into conflict with the public it is (or was originally) meant to serve. Thus, the most important implication of bureaucratic rhetoric for the public is that bureaucratic rhetorics serve to constantly re-achieve FLS for bureaucratic approaches and to repeatedly reaffirm the value of bureaucratic calculation and procedure over public input. That such far-reaching

issues are tied up in any attempt by the public to intervene in bureaucratic decision making suggests both the difficulties involved in intervening and the overriding importance of doing so.

Directions for the Future: The FDA and the Public

Two of the key themes of this project have been the inherent complexity of the Avastin decision and the broader complexity of science-based decision making, and so clear-cut, simple, ready solutions to the issues outlined here are not available. However, two possibilities present themselves as at least first-step approaches to breaching the growing gap, the potentially dangerous growing gap, between science-based regulatory bureaucracy and the citizens it is meant to serve. These are: admissions of contingency and movements toward care.

The first potential solution is a very simple one: the admission of contingency by the scientists involved in the making of regulatory decisions. The problem outlined in this project is largely one of a transformation from the ambiguity of scientific work to statements of absolute certainty by the makers of science-based policy. It is this transformation, in large part, that the public and patients object to. Again and again, they reiterate their rhetoric of pragmatism in the language of modality: we *might* get better, it *could* help. As Wynne (2011) puts it, however, “For political institutions the key question is often how to simplify an issue to manageable dimensions in the first place. It is usual to distil questions to their alleged essence, which means to simplify” (p. 36). As I have argued here, to simplify in the Avastin case is to deny the space for hope—the space for potential healing, for potential value—that resides for patients in the uncertainty of the science. Simply acknowledging that ambiguity and placing the “blame” as it were

for the necessity of simple yes/no answers where it belongs—with the necessity for immediate decision making inherent in the regulatory process—rather than implying or stating that the simplicity is inherent in the science, could produce a space in which the cause of much of the disagreement (regulatory procedure) could be more productively and directly debated.

The second possibility for some kind of rapprochement between the FDA and the public has been suggested by Latour (2003) himself. As he put it, “Can we devise another powerful descriptive tool that deals this time with matters of concern and whose import then will no longer be to debunk but to protect and care?” (p. 232). Although his target here was criticism itself, his interest in moving “from matters of fact to matters of concern” does offer a potential second possibility: a move toward incorporating a rhetoric of care into regulatory speech. Care offers a middle ground between expert authority and patient choice. The rhetoric of care has been described as “attention to relationship” (Cates & Lauritzen, 2001, p. 310). “Care,” write Cates and Lauritzen, “presents a context that begins with the assumption of connections to be met with appropriate responses, instead of radical individuality that must be adjudicated in terms of the rights of separation and authority” (p. 310). Thus, care provides the opportunity for experts to provide *relevant* and *appropriate* choices to patients, based on their understanding of a situation but also based on their relationship with the patient. In fact, it is this rhetoric of care that the public speakers constantly laud in their relationships with their own doctors, and it is the lack of relationship that drives their criticism of the fact that no breast cancer oncologists sit on the voting panel (none has a relationship, they argue, with real breast cancer patients).

Both of these suggestions share something in common: both would require the ODAC voting panelists to incorporate, within their role on the FDA panel, all of the multifaceted elements of their identities as *doctors*. As Keranen (2010) writes, doctors who also conduct research are caught in a dilemma, a “tension between physician and researcher,” and in the tension created by the randomized clinical trial, with its assumption that “doctors who treat can simultaneously be doctors who study” (p. 46). The ODAC panelists are caught in a similar tension, or as Keranen writes, “caught between two worlds—the mythos of the ancient and humane art of healing and the contemporary rigors of clinical science” (p. 46). As I will discuss below, the identity of the doctor is a complex, multifaceted one, yet the role of ODAC panelist seems to reduce that complexity to a singular role as purely objective research scientist. An incorporation by FDA speakers of the care aspects, and care rhetorics, of the physician—which according to their own statements the public and patients find more compelling—could help bridge the gap between the public and the FDA.

Implications for Science and Medicine

One of the key assumptions of bureaucracy, as demonstrated here, is the belief in achievable facticity: the assumption that there is a single, provable evidence base to answer any question of medicine or health. The other bureaucratic assumption that dovetails with this one is the belief that medical and health decisions should be made on the basis of that scientific facticity. Thus, the continual efforts of the ODAC committee to achieve facticity for a *single* version and interpretation of the scientific evidence and for the assumption that that evidence should be the one and only basis of decision making. The implications of these assumptions are problematic, especially given the

power bureaucratic institutions now have over both basic science work and clinical research. Remember that one scientist wrote that “most research, as well as universities and research institutes, is now funded by public agencies using taxpayers’ money” and is thus distributed, monitored, and often owned by bureaucratic organizations (Wolinsky, 2010, p. 664). Whatever assumptions bureaucratic agencies make about medicine, science, and facticity, those assumptions have outsized influence on all practitioners of medicine and medical research.

The primary finding of this project, then, in terms of the practice of medicine, is that bureaucracy requires facticity—so much so that it will manufacture it if necessary, and will manufacture it in direct opposition to those it claims to serve. The secondary effect of that manufactured facticity, I will suggest here, is to severely attenuate the definition and practice of medicine itself. Although demonstrating that bureaucracy actually has this effect on medicine will require considerable future research (for example, tracking changes in medical practice over time and in tandem with increased bureaucratic intervention in medical science), it is powerfully suggested by recent statements by several influential medical practitioners, as well as by the differences between what these practitioners say about medicine and the facticity the FDA attempts to achieve in the hearing.

The difference between what medical practitioners say about their work and what the FDA claims and assumes about facticity is essentially this: medical practitioners, like the public speakers at the hearing, nearly unanimously agree that theirs is a practice that involves complexity, multiple expertises, ambiguity, and a need to balance scientific evidence with individual patients’ widely varying disease progressions, personal beliefs,

and choices. Moreover, these practitioners nearly uniformly claim that the reduction of medicine to a pure reliance on “scientific evidence” or data is unquestionably a bad idea¹⁷.

Ironically, one of the most common arguments for the impossibility of reducing medicine to the scientific evidence alone is the insistence by doctors on “clinical judgment.” This is ironic because it is precisely this phrase, “clinical judgment,” that (as we saw in Chapter 3) the FDA speakers use to circularly support the proceduralism and facticity of their own decisions. The consensus among medical practitioners, however, appears to be that clinical judgment neither can nor should be reduced to a reliance on data or procedure, and that clinical judgment is itself too humanistic a concept—too invested in the individual—to be managed on the population level. As Kathryn Montgomery (2006) puts it in *How Doctors Think: Clinical Judgment and the Practice of Medicine*:

Medicine’s success relies on the physician’s capacity for clinical judgment. It is neither a science nor a technical skill (although it puts both to use) but the ability to work out how general rules—scientific principles, clinical guidelines—apply to one particular patient. This is—to use Aristotle’s word—*phronesis*, or practical reasoning. (n.p.)

In Weber’s terms, then, Montgomery is claiming that medicine in fact operates according to a rationality more closely aligned with the practical rationality of the public speakers than the procedural or formal rationality of the FDA. Even more forcefully, Montgomery goes on to explicitly oppose the reduction of medicine to scientific data: “The widespread misdescription of medicine as a science,” she writes, “and the failure to appreciate its

¹⁷ Perhaps most interestingly, almost all of the ODAC panel members are themselves medical practitioners when they are not sitting on FDA committees—which suggests, as I will argue in the next section, that it is their *role* in the hearing, rather than their *identity* as doctors or members of a scientific or medical community, that drives their rhetorical insistence on facticity.

chief virtue, clinical judgment or phronesis, amount to a visual field defect in the understanding of medicine” (n.p.). Such a claim is a strong implicit indictment of the FDA speakers’ attempts to define medicine generally, and clinical judgment specifically, as analogous with a pure reliance on data.

However, Montgomery is a sociologist of science whose work is merely based on hundreds of hours of experience with practitioners. It is of even greater interest that the practitioners themselves, in their own work for both academic and public audiences, express the same concepts of medicine and its relationship to scientific evidence. Jerome Groopman, an M.D. and writer of a number of popular works on medical thinking, agrees with Montgomery. In terms of the proper use of statistical evidence in medicine, for example, he writes, “When you can interpret statistics accurately, you can merge science with stories and fit single anecdotes into the larger context of all people who are treated” (Groopman, 2011, n.p.). In other words, far from denouncing individual patient experience as anecdote and claiming it as invalid *because* it is anecdote, Groopman argues that anecdotes fit into, inform, and complement population-level data sets. In *How Doctors Think* (not the same as Montgomery’s book, although both have the same title), Groopman goes further, claiming that “[o]f course, every doctor should consider research studies in choosing a therapy. But today’s rigid reliance on evidence-based medicine risks having the doctor choose care passively, solely by the numbers. Statistics cannot substitute for the human being before you” (Groopman, 2007, n.p.). In discussing the increasing role statistics and research data are playing in medical education, Groopman is even stronger in his disapproval: “I concluded,” he writes, “that the next generation of doctors was being conditioned to function like a well-programmed

computer that operates within a strict binary framework” (n.p.). Again, this description stands in direct opposition to the FDA’s approach: the formal, procedural rationality and the approve/deny mentality of the bureaucracy do function much like a “well-programmed computer” with a “strict binary framework.”

Jerome Lowenstein, in his classic *The Midnight Meal and Other Essays about Doctors, Patients, and Medicine* (2005), supports both the idea that the individual patient’s anecdotes and narratives are critical to proper medical decision making and the belief that medicine cannot and should not be reduced to reliance on research data. “As medicine comes to understand disease processes,” Lowenstein writes, “there is a tendency to substitute that understanding for the unique, unpredictable, uncanny sequence of events that make up the narrative, the experience of illness” (p. 71). Like Groopman, Lowenstein indicates that this shift toward complete reliance on research data is not only problematic but relatively new, a shift in direction. The increasing power of bureaucracies in funding, overseeing, and validating the results of almost all scientific and clinical research surely has some role in this shift. However, Lowenstein goes further, claiming explicitly that the reliance on data is a *reduction* of medicine to just one of its component parts—and that the other vital parts are humanistic, narrative, and individual. “The central role of narrative in medicine,” he claims, “is threatened by the reductionism that inevitably, and perhaps appropriately, follows the identification of fundamental unifying cellular and molecular mechanisms” (p. 71). Moreover, he argues, it is the role of the physician—and *not* the role of a body that makes decisions at the population level—to determine the relevance of research data to individual disease: “To fulfill the role of knowledgeable advisor to the patient, the physician must be ready to

critically evaluate the studies, to determine the degree to which the findings apply to the specific patient, and to interpret the findings and their significance for the patient” (p. 37). In all of these statements, Lowenstein argues that the growth in scientific knowledge about the underlying physical causes of disease, combined with the new focus on “evidence-based” medicine, amounts to a reduction of the medical field to just one aspect of its true complexity and innate ambiguity.

Lowenstein also suggests a reason for this reductionism: a desire to avoid responsibility and blame. Certainly one can argue that this is the reason for the FDA’s reduction of medical decision making to pure reliance on the data: the FDA’s primary concern is that it will become subject to a Congressional hearing and will lose funding and power. In the face of such potential losses, one of its primary objectives must be to create a case on which it can support its decision—to protect itself, in other words, from responsibility if bad outcomes occur. Lowenstein suggests that this is the reason for the unfortunately increasing commitment to research data and population-level outcomes among both medical practitioners and health agencies. “We act,” he writes, “as if the raw data will provide the answer and relieve us of responsibility” (p. 37). By extension, if the “raw data” are to provide relief from responsibility, they must be clear and relatively unambiguous; if there are no such data to support any particular decision in a case, they must be argued into existence. This is certainly what the FDA appears to be doing: asserting a level of facticity for the data that simply does not exist so that its decision can appear to rest not upon any individual’s or group’s subjective decision-making processes, but upon “the science”—the “raw data.”

Another important claim about the practice of medicine that conflicts with the FDA's reductionist presentation of "clinical judgment" as a pure reliance on research data is the claim that medicine in fact requires multiple expertises, that medicine and health are *not* "sciences" in the same sense that, for example, biology is a science. As Norman, Eva, Brooks, and Hamstra (2006) write in "Expertise in Medicine and Surgery," "Expertise in medicine requires mastery of a diversity of knowledge and skills" (p. 339). Certainly one of the knowledge bases that must be mastered is that of the basic sciences of biology and chemistry, but no amount of scientific knowledge is sufficient for expertise in medicine. In fact, these researchers found that expertise in medicine was accompanied by a *decrease* in reliance on such scientific knowledge: "experts," they write, "use less basic science in their explanations [of diagnoses and prescriptions] than medical students" (p. 343). Such a finding suggests that basic science knowledge is necessary but not sufficient for expertise in medicine—and, more importantly, suggests that basic science, the "raw data," is at best a single part of a multitude of elements that constitute expert medical decision making. As the authors put it, "The interplay between the formal knowledge of medicine and experiential knowledge has emerged as a central issue in understanding medical expertise" (p. 340). In other words, the matter of the relationship between the scientific data and the other, more humanistic or subjective elements of medical practice in determining good "clinical judgment" is not anywhere near as settled as the FDA speakers assert.

Finally, medicine is not reducible to science simply because patients' lives are at stake. As Collins and Pinch (2005) put it in *Dr. Golem: How to Think About Medicine*:

So as not to confuse the big and small questions we have to remember that medicine is not about one thing but two: medicine is a science, like other

sciences, but it is also a source of succor—a source of relief in times of distress. The two faces of medicine often conflict. One dimension of that conflict is urgency: medicine as a *science* has to try to get things right however long it takes, but medicine as *succor* has to provide an answer here and now. (p. 2)

These authors have identified precisely the tension at work in the hearing and the problem of allowing the bureaucratic (and thus facticity-necessitating and data-reliant) view of medicine continue to wield such overarching power over patients and doctors in their practice of medicine. The patients and other public speakers insist upon the acknowledgment of the “succor” aspect of medicine, while the FDA does not reject that appeal, but simply ignores it and makes its own claims on the basis of the presupposition that it is already proven to be incorrect and irrelevant to the matter at hand.

As the quote that makes up the title of this project indicates, even the FDA acknowledges that “sometimes there are differences of opinion as to what the data mean.” However, in its attempt to support its own procedures and the bureaucratic approach to public health generally, and to avoid the potential risks and responsibilities that necessarily accompany an ambiguous, complex understanding of medicine, the FDA does not, perhaps cannot, allow those differences of opinion to stand. Because its approach is scientific, it must “try to get things right however long it takes”—must achieve facticity no matter what the immediate cost for patients. However, unlike a scientific researcher who may be able to continue her work until the facts are at least largely certain or defensible, the FDA must make a decision whenever asked to do so. There is no option for the bureaucracy to wait for further science. It must say “yes” or “no” to patients immediately. In the face of this regulatory reality, the facticity manufacturing of the FDA is explicable: if on the one hand the bureaucracy does not have the time to wait until

“the science” on Avastin exists (a consensus about the facts and “what the data mean”), but on the other hand can only make a decision on the basis of that “science,” then it must create “the science”—select one interpretation of the data, achieve facticity for it, and certify that facticity through the votes of the panel of experts.

All of this would matter much less if it were not for the “long arm” of the regulatory bureaucracy. As Norman, Eva, Brooks, and Hamstra (2006) argue:

It is unlikely that a search for the single representation (whether ‘mental’ or theoretical) that fits all [medical expertise] is appropriate. Far more likely, there are multiple forms of expert knowledge, and each may be used to greater or lesser degree depending on the situation. (p. 346)

A strong reliance on the data may be absolutely appropriate to the making of regulatory decisions at the population level, whereas the incorporation of narrative, individual judgment, and the need for succor are all clearly equally important when making individual health decisions. The problem is that once the bureaucracy has spoken, the decision making that should be done at the individual or medical practitioner level is rendered impossible. A doctor may determine that, for myriad complex reasons, Avastin is the best choice for her individual breast cancer patient. However, because the FDA has constructed the science such that the drug has “no benefit” officially and in regulatory terms, it is essentially denied both patient and doctor as a recourse.

Implications for Rhetoric

The final question to be addressed here is, “If doctors, including oncologists, seem to agree that medicine is narrative, individual, and ambiguous and that a pure reliance on data is reductionist and problematic, why do the members of the ODAC panel—most of them doctors who treat patients in their lives outside the hearing room—

side so powerfully and unanimously with the bureaucracy in its limited, facticity-manufacturing concept of medical decision making?” This question suggests both the key implication of this project for rhetorical theory and the most potentially fruitful future studies that might come out of it.

The implication for rhetorical theory is the importance of interrogating role as well as community when analyzing an individual’s or group’s rhetorical commitments. Many studies have investigated the incredibly important function of communities—geographical, cultural, educational, etc.—on individuals’ uses of rhetoric. As was discussed in the introduction to this project, the focus of rhetorical theory has shifted, quite appropriately, from a strong focus on the individual rhetorical “genius” (the individual with a particular purpose who devised, on her own, a uniquely effective rhetorical strategy for the achievement of that purpose) to a more balanced understanding of the individual as “situated” within existing communities and community rhetorics that the speaker adopts and adapts—intentionally and consciously or otherwise—to the purpose at hand. James Wynn (2012), to take just one recent example, has explored this community aspect of the rhetorics of evolution in the 19th century. Wynne argues that the individuals who appear to have revolutionized evolutionary thinking by introducing novel ideas through novel rhetorical strategies (particularly rhetorical strategies that drew on the evidentiary power of numbers and mathematics), were actually drawing upon evidentiary rhetorics that were common and growing more so while and just before they were writing. Leah Ceccarelli, on whose methods I based much of my work (see Chapter 2), similarly explicated the effectiveness of certain discipline-altering works by seeing

them as adopting existing rhetorical strategies from multiple communities, rather than inventing new strategies for their new purposes.

This project suggests that a rhetor's role in a particular situation may be as powerful in shaping his rhetoric as his community memberships, and in some cases may be even more powerful. Even within a single one of the many communities an individual may belong to, that individual plays multiple roles. As Norman, Eva, Brooks, and Hamstra (2006) indicate, there are multiple types of medical expertise that may drive decision making in different situations; the medical practitioner who must state and justify a decision in each of these different situations will draw on these different expertises, and their associated rhetorical strategies, as appropriate.

Roles are especially important to understanding bureaucracy because roles are both so well-defined and so interchangeable in bureaucratic organizations. Roles in bureaucracies are well-defined in terms of what a particular individual in that role may do or say, but also in terms of *how* the individual must do or say it. So for example, the ODAC panel members at the Avastin hearing were operating under very specific guidelines as to what they were allowed to consider as evidence, what kinds of answers they were allowed to give, and what specific questions they were allowed to vote on. The doctors who spoke as members of the public had no such constraints. Moreover, the ODAC panel members spoke *as* spokespersons (however temporary) of the bureaucracy, whereas all the public speaker doctors appeared as advocates for their patients. As a result of these difference in *role*, these doctors, with their nearly identical backgrounds, training, and community identifications, employed rhetorical strategies that were in line

with the different purposes and decision-making strategies appropriate to the different aspects of medicine they were embodying.

Again, this is not to argue that the speakers for the FDA misrepresented themselves as doctors or members of the medical community. Rather, it helps explain why there are “differences of opinion as to what the data mean,” even among (outwardly) nearly identical members of the same community speaking about the same data at the same hearing. What it points to is the incredible power role can play in selecting among a speaker’s available rhetorical strategies. Moreover, it suggests that the problem in the hearing is not that medical decision making is not fully or adequately represented—in fact, between the various stakeholders, every aspect of medicine, and every role of the medical practitioner, is represented in some form—but that the bureaucratic speakers have such power that theirs is the only representation of or approach to medicine that is allowed value or validity. The hearing is in many ways itself a debate about the relative importance of the various roles a doctor plays—scientist, nurturer, advocate.

Unfortunately for the patients and for medicine itself, the FDA holds the power to predetermine the outcome in its own favor, and the multifaceted complexity of medicine, the ambiguity and inconclusiveness of clinical data, and the variety of roles doctors play in our society are reduced to the formalist, data-driven proceduralism of the bureaucracy.

Given the power that bureaucracy wields through funding, education, and so on, its reductionism affects medical practice in our society broadly, reducing the roles (and thus also the rhetorical resources) available to the doctor—as the doctors cited above noted. This indicates a potentially fruitful direction for future research based on this project: work that attempts to generalize my findings about bureaucracy’s reduction of

medicine and the effect of that reduction in limiting and attenuating the multiple and complex roles of the medical practitioner. In other words, future work will attempt to identify whether there is a relationship between the facticity-producing rhetoric of the medical bureaucracy and Groopman's sense that "the next generation of doctors [is] being conditioned to function like a well-programmed computer" and not to engage with what Lowenstein called "the unique, unpredictable, uncanny sequence of events that make up the narrative, the experience of illness."

Rhetoric and Complexity

Potentially even more interesting for rhetorical theory is the implication that "a rhetoric" (say, "the rhetoric of the FDA," or more broadly, "the rhetoric of science-based regulatory bureaucracies," or at the broadest level, "the rhetoric of science" or "the rhetoric of medicine") can be defined *in terms of* the reduction of complexity. In other words, the findings of this project suggest that one way to define "a rhetoric" is: a relatively stable, relatively consistent approach to reducing complexity through patterned symbol use for the achievement of certain outcomes, whether explicitly "intentional" or "purposeful" or not. It is important to remember that the reduction of complexity, despite the generally negative connotations of a term like "reductionism," is not a negative thing in and of itself; in fact, the reduction of complexity is both necessary and unavoidable, especially when faced with the need to make a decision. For example, this dissertation reduces the complexity of the FDA hearing on Avastin immensely; no single document could come close to handling the complexity of a nearly 700 page transcript of an interaction between human beings that was itself based on years of work and tens of thousands of supporting pages of documentation. One could identify, in fact, the specific

rhetorics with which I was making my own argument by identifying the *particular ways* in which my work reduces the complexity of the hearing—as it does and must.

This definition of rhetoric is useful, then, in redirecting our attention to something that *is always* happening when rhetoric is used—that must always be happening, that is inevitable. Working from this definition, the questions by which we would characterize “a rhetoric” would be:

1. What kinds of complexity does this rhetoric seek to reduce?
2. How does this rhetoric employ patterned symbol use (particularly language but not always language) to achieve these particular reductions in complexity?
3. What are the purposes and/or the effects of using these symbolic or linguistic patterns to reduce these particular types of complexity?

These are the questions I have attempted to begin answering here, and my own future work will move in the direction of applying this new definition of rhetoric to identify its affordances and limitations.

Following the Avastin Decision “Through Society”

A number of interesting future projects are also suggested by Latour’s (1987) admonition, from the subtitle of *Science in Action*, to “follow scientists [...] through society.” In the first place, it would be interesting to simply “follow the Avastin decision through society” to identify the ways in which the facticity achieved during the hearing is either upheld and strengthened, or critiqued and weakened, in the public forum. To do so would indicate the extent to which the decision is closed—the extent to which facticity achieved in a hearing truly exerts power in the larger society and is impervious to public

opposition—as well as the extent to which other media follow the lead of the FDA (or not) in maintaining that facticity.

In a similar vein, it would be interesting to identify how the lines are drawn in the public sphere according to which institutions, individuals, and media outlets use which of the rhetorics from the hearing. Presumably, the lines of debate are drawn in roughly the same ways, using roughly the same opposing rationalities and rhetorical strategies, in the public sphere as in the hearing. It would be beneficial to test this theory: to determine which groups in the public sphere identify with which groups in the hearing and how the public sphere debates pick up and use rhetorical strategies from the hearing itself. This would be particularly interesting in investigating the use of the particular notion of democracy as individual freedom of choice (the definition relied upon by the public speakers in the hearing) and the larger effect this particular “democracy” rhetoric is having upon health care and health decision making.

Another way that one could follow the FDA’s achieved facticity through society would be to investigate in greater detail the problematic concept, barely mentioned at the hearing but wrapped up in the facticity that is achieved about the drug, that Avastin offers “false hope.” This concept is used in the hearing to reiterate and support the notion that the apparent benefits of Avastin (as detailed by Genentech, found in at least one of the studies, and pointed out by the public speakers) are in fact illusory in some way. How, precisely, they are illusory and “false” is never explained, but that one small phrase, “false hope,” does get picked up and becomes something of a mantra in media representations of the Avastin decision. This is in part because one of the ODAC voting members wrote a letter to the *New England Journal of Medicine (NEJM)* describing why

he made the decision he did—using the phrase “false hope” three times in a letter of six short paragraphs and directly contrasting it with “hope” (the somehow real kind) twice (Sekeres, 2011, pp. 1454-1455). Others followed his lead, citing his letter as the authoritative final comment on the findings of the hearing (after all, it is much easier to cite a six-paragraph letter, especially from such a source as the *NEJM*, than to read 700 pages of transcript). One NPR news story, for example, quoted more than a third of the letter verbatim and reified Sekeres’ explanation in the story’s title: “Avastin for Breast Cancer: Hope versus False Hope” (Hensley, 2011, n.p.)

Although the hope versus “false hope” issue was not specifically related to the research questions being addressed here, it offers an interesting potential avenue for future research, allowing further investigation of the exact nature of the facticity achieved in the hearing as well as the ways that facticity was picked up and strengthened by certain media outlets. It is particularly interesting given a new interest in the concept of hope in medical and psychological research, where “false hope” is being found to be a rather illusory concept in itself—especially given that any kind of hope appears to improve both psychological and clinical outcomes for patients. As one prominent group of hope researchers puts it, “if false hope presently exists, [...] we have not found it” (Snyder, Rand, King, Feldman, & Woodward, 2002, p. 1017). In fact, the hope that the breast cancer patients express is surprisingly realistic: they admit that they are almost certainly going to die of their disease and are willing to accept the admittedly limited benefits Avastin offers with their eyes open to its potential side effects.

The “false” hope in the hearing, if such a thing exists, may well be the ODAC members’, as expressed in their implicit belief in the ability of science to fix any medical

problem. As they continually say, one major reason not to approve Avastin for breast cancer is so that more trials, of both Avastin and other drugs, can be conducted—so that a cure can be found. In other words, their decision is based on the hope that given time, science will be able to eliminate breast cancer as a disease, rather than “only” reduce pain and delay disease progression. Compared to the realistic and bounded hopes of the breast cancer patients, the ODAC members’ continued insistence on the only “real” hope being that of a complete cure seems the more illusory. Clearly, this is merely a brief outline of the potential “hope” and “false hope” work that could be done based on this hearing; this is one of the most intriguing, and potentially most fruitful, areas of study for the extension of the present work.

Conclusion

The main finding of this case study is that there is no such thing as “the science” of Avastin but that the bureaucracy must act as if there is—must create it rhetorically if necessary—in order to perform its functions. Moreover, this necessity for achieving facticity in situations in which the evidence is inconclusive has potentially far-reaching and damaging consequences for public trust in bureaucratic agencies, for patients, and for the practice of medicine itself. (Potentially, this applies for other fields as well, a claim I will pursue in future research about facticity-achievement as the underlying strategy and purpose of bureaucratic rhetorics more generally.) As both public and academic understandings of science increase in complexity and sophistication, the traditional decision-making mechanisms of science-based bureaucracy will be open to more and more scrutiny and criticism, but will also continue to have the power to attenuate the functions, roles, purposes, and applications of science in our society. Medicine, in

particular, is complex, ambiguous, individual, and emotional. While the work of a bureaucratic, federal-level regulatory agency may depend on a strong reliance on data, that agency must work to ensure that it is not indirectly reducing the vital complexities of meaning and practice inherent in both science and medicine.

The bureaucratic insistence on achievable facticity as the only basis for decision making was born in the understandings of science popular in the late 19th and early 20th century, and it is high time to consider whether such approaches remain valid in the face of new sciences, new technologies, and new understandings of the multiple roles of medicine in our lives. This is particularly important because, despite the issues uncovered here and in other critiques of bureaucratic governance, a return to the unregulated period before the creation of the FDA is not to be desired. Bureaucratic rhetorics and decision-making processes, in other words, must change such that they actually embrace and account for the complexities of modern science and medicine, rather than engaging in the trust-undermining theater of fake participation that is so evident in the Avastin hearing.

APPENDIX

Excerpt from Avastin Transcript, June 29

(Bolded sections are those discussed in the text.)

DR. BALIS: We talked a little bit about quality of life, since I think we're going to have difficulty with overall survival as a potential endpoint. One of the points that was made as a secondary endpoint was that the drug produced more objective responses than the chemotherapy alone.

From Dr. O'Shaughnessy's talk, I gather that most of these patients who are treated with the drug are symptomatic at the time they get it. And the question I have for her is, **is response a surrogate for relief of symptoms in these patients?**

DR. O'SHAUGHNESSY: Yes. **Response rate can be helpful for two groups of patients, one, those who are already symptomatic; there's no question. The higher the response rate, the higher the percentage of patients who will get clinical benefit, relief of symptoms.**

The other group are people who if they do not get a response, that within a relatively short period of time, they will have significant symptoms, or threatening end organ functions. A response for those patients as well, I believe, translates into clinical benefit. So I think those are the two places, so that doesn't mean everybody, but it means those particular patients with usually symptomatic, more rapidly advancing disease.

DR. MIDTHUN: Dr. Sekeres?

DR. SEKERES: Can I ask a follow-up question, Dr. O'Shaughnessy? **So did response correlate with an improvement in the FACT-B scores** in those patients?

DR. O'SHAUGHNESSY: I'm going to have to turn to Genentech here to ask them about that.

DR. REIMANN: As you know, **response can happen at different time points on the study, and the FACT-B instrument was collected also at different time points of the study. So we don't have a correlation between changes in FACT-B score.** We did look, but we didn't see a correlation, but it is a bit challenging, based on the timing of the FACT-B and the timing of the tumor assessments.

DR. SEKERES: **Though, presumably, people who were responding at one time point would be responding to when the next FACT-B would be administered to those patients?**

DR. REIMANN: **We don't have a correlation of FACT-B changes and objective response rate in AVADO.**

DR. SEKERES: **So there is no correlation between a validated instrument measuring quality of life and response to Avastin?**

DR. REIMANN: It is a valid instrument in assessing quality of life. I think the question is, **is it sensitive in this patient population?** In a front-line setting, in a typical front-line population, probably fewer than 20 percent of patients are symptomatic. And that's the studies that are done by any sponsors. They have a mixture of ECOG zero and 1 patients. So I think **you'd really want to focus on symptomatic patients, and that's a smaller group.**

DR. SEKERES: **So I think probably, the best instrument out there for measuring**

quality of life, in the U.S. at least, is the FACT for a number of different cancers, including breast cancer. And we don't have a clear correlation between improvement in a woman's well-being, how she reports it herself and response to a drug.

I was once taught that the plural of anecdote is not data. So we each have one story of somebody who felt better while responding, but if the facts don't support that, then that's not something that we can rely on.

DR. MIDTHUN: Other comments? Dr. Wilson?

DR. WILSON: I think this is a very slippery slope. **Response is an arbitrary number** determined by the RECIST, and it's got a threshold. We all oncologically know well that patients can have significant improvement in symptoms without hitting a response endpoint. And so I just want to echo what Dr. Sekeres said, and that is that, yes, if you have a PR or more and you're symptomatic, then the chances are you will have amelioration of your symptoms. However, you can have amelioration of bone pain, et cetera, without a bona fide PR. And so I think that you can't use the response numbers as a surrogate for that.

Then, of course, that's confounded by the fact that only a minority number of folks, I understand, even had a truly symptomatic disease. So I think we're back to ground zero in terms of, **we have no evidence that the treatment arm improved quality of life.**

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